Exhibit 5

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation

THIS DOCUMENT RELATES TO:

Bondurant v. Johnson & Johnson,
No. 3:19-cv-14366

Converse v. Johnson & Johnson,
No. 3:18-cv-17586

Gallardo v. Johnson & Johnson,
No. 3:18-cv-10840

Judkins v. Johnson & Johnson,
No. 3:19-cv-12430

Newsome v. Johnson & Johnson,
No. 3:18-cv-17146

Rausa v. Johnson & Johnson,
No. 3:20-cv-02947

CASE NO.: 3:16-md-02738

MDL No. 2738

Expert Report of John Kornak, Ph.D.

May 28, 2024

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I. QUALIFICATIONS

1. I am a Professor in Residence of Biostatistics in the Department of Epidemiology and Biostatistics in the School of Medicine at the University of California, San Francisco (UCSF). In addition, I am the Head of the Health Data Science Program and the Director of the UCSF Biostatistics Consulting Unit, part of the UCSF Clinical and Translational Sciences Institute. I earned my Bachelor of Science (B.Sc.) in Mathematics with Statistics from the University of Nottingham, UK, graduating in 1996. I received my Doctor of Philosophy (Ph.D.) degree in Statistics from the University of Nottingham, UK, in 2000. My training and expertise are in Mathematics and Statistics/Biostatistics.

2. I have spent more than 20 years teaching and researching biostatistics and have experience in research applied across a number of disciplines, including statistical methodology, epidemiology, radiology, neurology, oncology, and engineering. My research program at UCSF has been focused on developing and applying statistical approaches to aid the understanding of biological processes from medical imaging data. I am internationally recognized in the research areas of statistical image analysis, statistical image reconstruction, statistical analysis of multi-modality imaging data, longitudinal analysis of clinical imaging data, and statistical imaging methods for the study of dementia and breast cancer. Furthermore, I have been, and continue to be, the lead statistician on many large-scale collaborative research projects, most of which are funded by the National Institutes of Health (NIH), including observational studies, clinical research projects, and clinical trials.

3. During my career, I have created and taught masters-level programs and classes in Health Data Science, Machine Learning, and Applied Biostatistics, for the Biomedical Sciences, including topics such as advanced statistical regression methods. I also serve as a mentor and supervise graduate students at the masters, doctoral, and postdoctoral levels, as well as junior faculty members in the fields of bioengineering, biostatistics, epidemiology, neurology, and clinical research training.

4. Since 2014, I have served as the Director of the Biostatistics Consulting Unit (BCU) in the UCSF Clinical and Translational Science Institute (CTSI). The BCU provides campus-wide statistical consultation and collaboration, including help with optimal experimental design, data

analysis, reporting and interpretation of results, and drafting or editing grant and paper statistical sections. As Director of the BCU, I manage over 20 employees, including faculty consultants and analysts, and I continue to perform consultations as Director of the unit.

5. I have received numerous honors and awards for my work in the field of biostatistics, including being elected Vice-President of Biostatistics (2006) and subsequently President of the Bay Area Chapter of the American Statistical Association in 2008, and being awarded the Consultant of the Year award three times at UCSF (in 2009 for Consistent Excellence, in 2010 for Impact, and in 2011 for Excellence). I have also been elected Council of Chapters Representative for the Bay Area Chapter of the American Statistical Association, and in 2016, I was elected Chair of the Statistics in Imaging Section for the American Statistical Association. I have been a fellow of the Royal Statistical Society since 1998. I have been selected as a fellow of the American Statistical Association in 2024.

6. I have authored and published more than 150 peer-reviewed publications, review articles, and book chapters. A copy of my curriculum vitae is attached hereto as **Appendix A**. It summarizes my educational and professional background and includes the above-mentioned list of authored publications, research projects and grant funding, lectures given, teaching responsibilities, and faculty members and students mentored. I have not provided testimony at trial or deposition during the last four years.

7. I am being compensated at my hourly rate of $700. My compensation is not contingent in any way or based on the content of my opinion or the outcome of this matter.

II. ASSIGNMENT

8. I have been retained by counsel for Johnson & Johnson and LLT Management LLC to review and provide expert analysis, opinion, and testimony regarding the article "Intimate Care Products and Incidence of Hormone-Related Cancers: A Quantitative Bias Analysis" authored by Katie O'Brien, Nicholas, Wentzensen, Kemi Ogunsina, Clarice R. Weinberg, Aimee

D'Aloisio, Jessie Edwards, and Dale Sandler published in the *Journal of Clinical Oncology* on May 15, 2024 ("O'Brien (2024)")[1] and the related literature.

9. In forming my opinions and conclusions, I have reviewed and considered the documents cited herein, such as documents produced in this litigation, as well as various public and private materials. **Appendix B** is a list of references considered in preparing my report. I have also relied on my years of academic and professional experience as a biostatistician, including my experience in mathematics, statistics, and real-world applications of statistical and mathematical methods, particularly in clinical fields.

III. SUMMARY OF OPINIONS

10. O'Brien (2024)'s inclusion of retrospective information on genital talc use drives the authors' main conclusion. When O'Brien (2024) uses only data on genital talc use that was collected prospectively, the authors find that—consistent with previous academic literature co-authored by Dr. O'Brien—there is no statistically significant association between genital talc use and ovarian cancer.

11. In performing the retrospective analysis, O'Brien (2024) "imputes," "corrects," or assumes the genital talc use of large subsets of women to account for missing or contradictory data on genital talc use. While the authors find a positive and statistically significant association between genital talc use (based on these adjustments) and ovarian cancer, the authors' "imputations" of, "corrections" to, and assumptions regarding genital talc use make their analysis flawed and unreliable. Specifically:

a. O'Brien (2024)'s primary finding that genital talc use was associated with ovarian cancer hinges on the authors' reclassification of women who never indicated genital talc use as genital talc users.

b. O'Brien (2024)'s "imputation" of genital talc use exacerbates the "recall bias" problem.

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[1] O'Brien, K. M., Wentzensen, N., Ogunsina, K., Weinberg, C. R., D'Aloisio, A. A., Edwards, J. K., & Sandler, D. P. (2024). Intimate care products and incidence of hormone-related cancers: A quantitative bias analysis. *Journal of Clinical Oncology*, JCO-23 ("O'Brien (2024)").

c. O'Brien (2024)'s chosen imputation method is inappropriate for the dataset that the authors use.

d. O'Brien (2024)'s "imputed" genital talc use is likely a poor proxy for a woman's actual genital talc use.

e. O'Brien (2024)'s "imputations" of genital talc use rely on circular logic.

f. O'Brien (2024) "imputes," "corrects," or assumes an unreliably large share of the authors' data on genital talc use.

g. O'Brien (2024)'s "imputed," "corrected," or assumed genital talc use data rely on inconsistent questions across Sister Study enrollment and follow-up questionnaires.

12. O'Brien (2024)'s estimated hazard ratios are inflated and not robust.

a. When "imputing," "correcting," or assuming the genital talc use of women in the Sister Study sample, O'Brien (2024) makes several decisions that classify women as genital talc users or nonusers that bias upward the authors' estimated hazard ratios ("HR") and inflate their estimate of the association between genital talc use and ovarian cancer.

b. Per the authors' own calculations, O'Brien (2024)'s result that genital talc use is positively and statistically significantly associated with ovarian cancer is unstable and sensitive to minimal perturbations in the "imputed" and "corrected" data on genital talc use.

13. O'Brien (2024)'s "recall bias"-"corrected" estimates of the association between genital talc and ovarian cancer are flawed and unreliable.

a. O'Brien (2024) assesses "recall bias" under only a very narrow and specific set of circumstances.

b. O'Brien (2024) overstates the conclusions that can be drawn from the authors' investigation of the effect of "recall bias" on their estimated association between genital talc use and ovarian cancer.

14. O'Brien (2024)'s lack of a pre-specified analysis plan renders the authors' conclusions flawed and unreliable.

IV. SUMMARY OF O'BRIEN (2024)

15. O'Brien (2024) purports to analyze the potential "association between intimate care products and female hormone-related cancers," including the potential association between genital talc use and ovarian cancer.[2] The authors state that although "the relationship between genital powder use and ovarian cancer has been especially well studied," prior results have been subject to "concerns about recall bias and exposure misclassification" that the authors claim preclude a "clear consensus."[3]

16. The authors use data from the Sister Study, a "US-based cohort study" that "enrolled 50,884 women who had a sister with breast cancer."[4] Data on the use of genital talc products "were collected at enrollment (2003–2009) and follow-up (2017–2019)."[5] At enrollment, survey participants were asked three questions about genital talc use:[6]

a. "During the ages of 10–13, about how often did you apply talcum powder to a sanitary napkin, underwear, diaphragm, cervical cap, or directly to your vaginal area?" (Choices: "Did not use," "Sometimes," "Frequently," or "Don't know")

b. "In the past 12 months, how frequently have you applied talcum powder to a sanitary napkin, underwear, diaphragm, cervical cap, or directly to your vaginal area?" (Choices: "Did not use," "Less than once a month," "1–3 times per month," "1–5 times per weeks," "More than 5 times per week")

c. "In the past 12 months, what types of talcum powder have you usually used on a sanitary napkin, underwear, diaphragm, cervical cap, or your vaginal area?" (Choices: "Did not use," "Powder," "Spray")

At follow-up, survey participants were asked one or more questions about genital talc use:

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[2] O'Brien (2024), p. 1.

[3] O'Brien (2024), pp. 1–2.

[4] O'Brien (2024), p. 1.

[5] O'Brien (2024), pp. 2–3.

[6] Personal Care Questionnaire, The Sister Study, available at https://sisterstudy.niehs.nih.gov/English/images/docs/PersonalCare-v3-508.pdf ("Enrollment Questionnaire").

a. "Have you ever applied talcum powder to a sanitary napkin, tampon, underwear, diaphragm, cervical cap, or directly to your vaginal area?" (Choices: "No," "Yes")[7]
b. [Only if respondent answered "Yes" in a.] "How old were you when you first used talcum powder on or near your vaginal area?" (Fill in age)
c. [Only if respondent answered "Yes" in a.] "Have you used talcum powder on or near your vaginal area in the past 12 months?" (Choices: "No," "Yes")
d. [If respondent answered "No" in c.] "How old were you when you last used talcum powder on or near your vaginal area?" (Fill in age)
e. [If respondent answered "Yes" in a.] "Did you use talcum powder on or near your vaginal area in your teens?...In your 20s?...In your 30s?...In your 40s?…In your 50s?"] (Choices: "No," "Yes")

Data on cases of ovarian cancer were identified through self-reporting and "verified via medical reports, when possible, with some fatal cases confirmed through the National Death Index or death certificates" current as of September 2021.[8]

17. Because their goal was to estimate the association between genital talc use and ovarian cancer, O'Brien (2024) required data on Sister Study participants' genital talc use. The authors, however, claim that they could not rely solely on the actual data generated by the questionnaire for two reasons. First, some survey respondents offered contradictory answers in the enrollment and follow-up surveys. Specifically, some respondents indicated in one survey that they were genital talc users but indicated in the other survey that they were genital talc nonusers during the same period of time. Such inconsistent responses are problematic because it is not clear whether a woman providing contradictory answers was or was not a genital talc user. Second, some survey respondents did not provide information about their genital talc use in either (or both) waves of the survey. For instance, some respondents declined to answer or left blank the question about genital talc use in the enrollment survey and/or declined to answer, left blank, or were unable to complete (e.g., due to death) the question about genital talc use in the follow-up

[7] The Sister Study, Health, Medical History and Lifestyle, available at https://sisterstudy.niehs.nih.gov/English/images/docs/SIS_DFU4_2018_vA_07182018.pdf ("Follow-Up Questionnaire").

[8] O'Brien (2024), pp. 1, 3.

survey. When participants provided an answer on only one of the surveys, the authors did not know whether the single datapoint they had on the respondents' genital talc use was accurate.

18. When estimating the association between genital talc use and ovarian cancer, O'Brien (2024) purports to account for "exposure misclassification" (contradictory responses) and missing data. To account for potential exposure misclassification and "correct" for missing data (particularly at follow-up), the authors implement four sets of assumptions:

a. "No Corrections, Fill in Missing" ("Scenario 1"): In this scenario, the authors assume that a participant's genital talc use is consistent with what she indicated on the enrollment survey. If the participant did not provide an answer about genital talc use on the enrollment survey, then the authors assume that the participant's genital talc use is consistent with what she indicated on the follow-up survey. Among participants who did not provide an answer about genital talc use on either the enrollment or the follow-up survey, the authors assume that 35% were genital talc users (which matches the ever use proportion at baseline per Table 1).[9] Furthermore, if the participant indicated never use at baseline but said she was a user at follow-up only in time intervals that would not imply a contradiction, then the participant was labeled as an ever user.

b. "Fill in Missing, Correct Contradictory Data, Extreme Unexposed" ("Scenario 2"): In this scenario, the authors "added [to Scenario 1] a correction for contradictory data"[10] in which they adjust the data on genital talc use for participants who indicate genital talc use in one survey, but not the other, in such a way that they are contradictory. Among women who indicated at enrollment that they were not genital talc users, but then at follow-up indicated genital talc use at ages that contradicted their enrollment response, the authors assume arbitrarily that 80% were genital talc users. Among women who indicated at enrollment that they were genital talc users, but then at follow-up indicated that they were never genital talc

[9] O'Brien (2024), Table A5.

[10] O'Brien (2024), p. 4.

users, the authors arbitrarily assume that 90% were genital talc users.[11] All participants who stated that they were not genital talc users at enrollment and who did not answer the question about genital talc use at follow-up, were categorized as nonusers.

c. "Fill in Missing, Correct Contradictory Data, If Undefined (unexposed at enrollment, but missing follow-up) Assume Exposed Extreme Exposed" ("Scenario 3"): In Scenario 3, the authors "included the contradictory data correction," as in Scenario 2, but categorized all participants who stated that they were not genital talc users at enrollment and who did not answer the question about genital talc use at follow-up as genital talc users.[12]

d. "Correct Contradictory Data, Use Multiple Imputation to Fill in Missing or Undefined" ("Scenario 4"): In Scenario 4, the authors state that they "used multiple imputation with chained equations…to generate covariate-informed probabilistic imputations of the exposure status of participants" who indicated they were nonusers of genital talc at enrollment but did not provide an answer about genital talc use at follow-up.[13] (I explain the authors' "imputation" method in more detail in Section VI.B.) The authors "consider [this scenario their] best estimate of the true association" between genital talc use and ovarian cancer "in the absence of recall or other unknown biases."[14]

Under each of these scenarios, the authors "impute," assume, or randomly select whether or not a participant used genital talc for 38% of the sample, but 54% of all ovarian cancer cases.[15]

19. For each of their scenarios, the authors implement "Cox proportional hazards models to estimate hazard ratios" ("HR") of the alleged association between genital talc use and ovarian

[11] O'Brien (2024), Table A5.

[12] O'Brien (2024), Table A5.

[13] O'Brien (2024), p. 4, Table A5.

[14] O'Brien (2024), p. 4.

[15] O'Brien (2024), Table A5. See also Section VI.F of this report.

cancer.[16] For Scenario 1, the authors find a positive, but not statistically significant relationship between genital talc use and ovarian cancer (HR of 1.07).[17] When implementing their adjustment scenarios to account for "exposure misclassification," the authors claim that "genital talc use was positively associated with ovarian cancer."[18] In Scenario 2, the authors compute an HR of 1.17, but this does not achieve statistical significance, and in Scenario 3, the authors compute an HR of 3.34, which is statistically significant, but that the authors acknowledge is unrealistic.[19] Under their preferred adjustment for "exposure misclassification," Scenario 4, the authors estimate an HR of 1.82 with 95% confidence interval (CI) of (1.36 to 2.43).[20] However, the authors note that they considered this approach as "our best estimate of the true association in the absence of recall or other unknown biases."[21]

20. The authors also claim to "investigate[] the potential impact of recall bias on the association between genital talc use and ovarian cancer"[22] Although the authors do not define "recall bias" in O'Brien (2024), O'Brien (2023) defines this as "over-reporting of genital talc use among those with a history of ovarian cancer"[23] and O'Brien (2020) notes that "recall bias" may be related to the "recent surge in talc-related lawsuits and media coverage."[24] Indeed, consistent

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[16] O'Brien (2024), p. 1. A hazard ratio ("HR") is "[a] measure of how often a particular event happens in one group compared to how often it happens in another group, over time," where an HR of one "means that there is no difference in survival between the two groups." See National Cancer Institute Dictionary of Cancer Terms, "Hazard Ratio," National Institute of Health, available at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/hazard-ratio, accessed on May 22, 2024. In their analysis, the authors use age as the time variable and begin counting time from enrollment until the age of diagnosis with cancer, death, refusal to answer a follow-up questionnaire, or September 2021. The authors also purport to adjust for confounding factors and demographic characteristics such as race, ethnicity, education level, body mass index, age at menarche, hormonal birth control use, menopausal status, parity, hormone therapy use, geography, and alcohol and tobacco use.

[17] O'Brien (2024), pp. 9, 12, Table 2.

[18] O'Brien (2024), p. 1. Without adjustments for "exposure misclassification," the authors estimate an HR of 1.07. See O'Brien (2024), Table 2.

[19] O'Brien (2024), Table 2, p. 3.

[20] O'Brien (2024), Table 2.

[21] O'Brien (2024), p. 4.

[22] O'Brien (2024), p. 4.

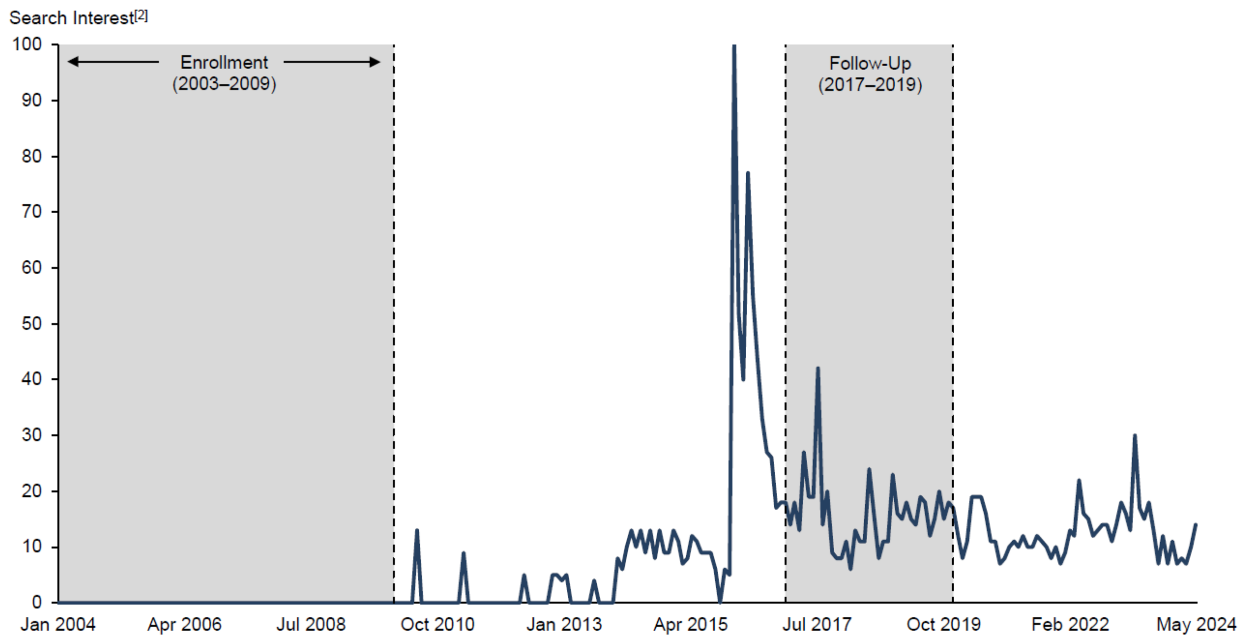
[23] O'Brien, K. M., Ogunsina, K., Wentzensen, N., & Sandler, D. P. (2023). Douching and genital talc use: patterns of use and reliability of self-reported exposure. Epidemiology, 34(3), 376-384 ("O'Brien (2023)") at p. 383.

[24] O'Brien, K. M., Tworoger, S. S., Harris, H. R., Anderson, G. L., Weinberg, C. R., Trabert, B., ... & Wentzensen, N. (2020). Association of powder use in the genital area with risk of ovarian cancer. Jama, 323(1), 49-59 ("O'Brien (2020)") at p. 50.

with this "recall bias" concern, interest in "talc" and "cancer" (searched together) was heightened before and during the fielding of the follow-up questionnaire, as measured by Google searches.

Exhibit 1

Google Search Interest for "Talc Cancer" in the United States[1] (January 2004–May 2024)



Source: Google Trends
Note:
[1] Search interest is shown for the search term "talc cancer" between January 2004 and May 2024 (solid blue line). Google Trends data are unavailable prior to January 2004. Data are current as of May 28, 2024.
[2] Google scales search interest by setting the month with the maximum number of searches in a month across the whole period to 100.

21. To attempt to account for "recall bias," the authors layer on top of Scenario 4 a series of "corrections" that "chang[e] the exposure status of a specified percentage of women with certain characteristics" to be considered either "nonusers" or "infrequent, short-term users."[25] The authors consider several sets of "corrections."

a. In the authors' first set of recall bias "corrections," the authors recode a proportion (10%–90%) of ovarian cancer cases as genital talc nonusers if the participant was a nonuser or missing genital talc use status at enrollment and was classified as a user based on the follow-up survey or "imputation."

[25] O'Brien (2024), Appendix 1.

b. In the second set of recall bias "corrections," the authors modify their first set of "corrections" by reclassifying only infrequent or short-term genital talc users. Specifically, they recode a proportion (10%–90%) of the subset of ovarian cancer cases classified as infrequent or short-term genital talc users as genital talc nonusers.

c. In the third set of recall bias "corrections," the authors assume a proportion (5%–25%) of participants without ovarian cancer who were labeled as genital talc nonusers were instead infrequent or short-term genital talc users.

22. O'Brien (2024) finds that "[d]ifferential reporting of genital talc use by cases and noncases" (i.e., recall bias), "likely produces positive bias," although certain "corrections" implemented to address it "still resulted in HRs above 1.0."[26] For example, when authors make the first recall bias adjustment and recode 25% of ovarian cancer cases as described above, the estimated HR for the association between genital talc use and ovarian cancer declines from 1.82 to 1.41.[27]

23. The authors conclude that "[their] findings support the hypothesis that there is a positive association between genital talc use and ovarian cancer incidence."[28] However, they acknowledge that "[t]hese results do not establish causality and do not implicate any specific cancer-inducing agent," and that "there is still uncertainty as to how much recall bias and missing data could upwardly bias effect estimates."[29]

V. O'BRIEN (2024)'S RESULTS THAT ARE BASED ON PROSPECTIVE ANALYSIS SHOW NO ASSOCIATION BETWEEN GENITAL TALC USE AND OVARIAN CANCER

24. O'Brien (2024) provides a set of results that are based purely on participants' prospective assessment of their genital talc use. In a prospective analysis, the "exposure" (i.e., genital talc

[26] O'Brien (2024), p. 1.

[27] O'Brien (2024), Table 3.

[28] O'Brien (2024), p. 14

[29] O'Brien (2024), pp. 13–14.

use) is measured *before* an individual experiences the "outcome" (i.e., ovarian cancer). A prospective analysis is advantageous because it diminishes the prospect for "recall bias" insofar as genital talc use is defined prior to the participants observing their outcome (ovarian cancer status) and also prior to the media coverage that O'Brien (2020) claims affects the reliability of the retrospective genital talc data.[30]

25. Several prospective analyses fail to show a statistically significant relationship between genital talc use and ovarian cancer. O'Brien (2024) performs a prospective analysis and estimates an HR of 1.02 summarizing the association between genital talc use and ovarian cancer with a corresponding 95% confidence interval of 0.79–1.33.[31] This finding is consistent with other academic literature, including prior papers co-authored Dr. O'Brien, which also use only prospectively collected data on genital talc use from the Sister Study. For example:

a. Gonzalez (2016) uses data on ovarian cancer incidence from 2003 through July 2014 and estimates an HR summarizing the association between genital talc use and ovarian cancer of 0.73 with a 95% confidence interval spanning 0.44–1.20.

b. O'Brien (2020) uses data on ovarian cancer incidence from 2003 through September 2017 and estimates an HR summarizing the association between genital talc use and ovarian cancer of 1.02 with a 95% confidence interval spanning 0.76–1.38.[32]

c. Chang (2024) use data on ovarian cancer incidence from 2003 through October 2020 and estimate an HR summarizing the association between genital talc use and ovarian cancer of 1.06 with a 95% confidence interval spanning 0.91–1.24.[33]

26. While these studies relying only on survey participants' responses about their genital talc use recorded prospectively find no evidence of an association between genital talc use and ovarian cancer, O'Brien (2024)'s inclusion of retrospective information on genital talc use leads

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[30] See O'Brien (2020), p. 50.

[31] See Section VI.A of this report.

[32] See O'Brien (2020).

[33] Chang, C. J., O'Brien, K. M., Keil, A. P., Goldberg, M., Taylor, K. W., Sandler, D. P., & White, A. J. (2024). Use of personal care product mixtures and incident hormone-sensitive cancers in the Sister Study: a US-wide prospective cohort. *Environment International*, *183*, 108298 ("Chang (2024)"), Online Appendix Table S4.

to the authors' main result. Specifically, only when O'Brien (2024) includes retrospective information on genital talc use do the authors find a positive and statistically significant HR.[34]

VI. O'BRIEN (2024)'S "IMPUTATIONS" OF, "CORRECTIONS" TO, AND ASSUMPTIONS REGARDING GENITAL TALC USE GENERATE FLAWS AND UNRELIABILITY IN THEIR ANALYSIS

27. As described in Section IV, when the authors incorporate retrospective data on genital talc use into their analysis, O'Brien (2024) "imputes," "corrects," or assumes the genital talc use for Sister Study participants. In this section, I explain why these "imputations" of, "corrections" to, and assumptions regarding genital talc use render O'Brien (2024)'s analysis and results flawed and unreliable.

A. O'Brien (2024)'s Results Hinge on Categorizing as Genital Talc Users Women Who Never Indicated Genital Talc Use

28. As described above, when O'Brien (2024) uses the Sister Study data "as is" in a prospective manner, they find no statistically significant association between genital talc use and ovarian cancer. Only when the authors "change" participants' responses to the questions or "create" participants' responses when data are missing (which occurs for 38% of the sample and 54% of ovarian cancer cases) do the authors find a statistically significant association.[35] In this section, I walk through the authors' different "scenarios" that reflect different manipulations of participants' responses. In particular, I explain how they differ from the prospective analysis and

[34] See O'Brien (2024), Table A2. When defining exposure status based on the enrollment questionnaire alone (i.e., prospectively), O'Brien (2024) finds that 28% of participants used genital talc, and the HR for the purported relationship between genital talc use and ovarian cancer was 1.02 and not statistically significant. Furthermore, the departure in the estimated HR from 1.0 is small compared to the 95% CI of 0.79–1.33; the CI provides an indication of uncertainty in the estimate and gives a plausible range of values for the true HR that are in agreement with the data. That is, there is no clear evidence that those who use genital talc are any more likely to develop ovarian cancer compared with those who do not report talcum powder use. By contrast, O'Brien (2024) reports that when exposure status is defined by using the detailed follow-up (i.e., retrospectively), 53% report genital talc use. Given that this increased fraction includes disproportionally more women who have developed ovarian cancer (at least in part due to recall bias), the HR for this group is elevated to 2.65 with a 95% confidence interval ranging from 1.91–3.70.

[35] See Exhibits 2–3 of this report. See also O'Brien (2024), Table A5.

then highlight the reliance of O'Brien (2024)'s specific findings on their departures from the baseline analysis.

29. The starting point for my exposition is O'Brien (2024)'s "baseline" analysis that is free of any sample manipulation and similar to approaches used by similar sets of authors in their past work on this topic, including O'Brien (2020), published in *JAMA*.[36] In this baseline analysis, relegated to O'Brien (2024) Appendix Table A2, the authors find that the use of genital talc has an HR of 1.02 with a 95% CI (0.79 to 1.33) on the risk of developing ovarian cancer.[37] This result is close to one (i.e., no effect), indicating a lack of evidence that women who used and did not use genital talc have any difference in their rates of developing ovarian cancer.[38]

30. O'Brien (2024)'s baseline analysis has two distinguishing features. First, it uses only prospective information to assign women to "never" or "ever" use of genital talc.[39] That is, a woman is a genital talc user if she stated so during the enrollment survey in the mid-to-late 2000s, *before* any ovarian cancer diagnosis. Second, O'Brien (2024)'s baseline analysis omits the small number of women (approximately 1.5% of the sample) who are missing enrollment survey information about genital talc use entirely.[40]

31. However, rather than present the baseline result in Table A2 as their main result, O'Brien (2024) instead presents four "scenarios" that depart from the baseline in how the authors classify (and sometimes even reclassify) whether or not a woman was a genital talc user. Below, I explain each scenario, including why the authors' manipulation of the data sample leads to statistically flawed, unreliable, and inflated estimates of the association between genital talc use and ovarian cancer.

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[36] See O'Brien (2020).

[37] O'Brien (2024), Table A2.

[38] Moreover, it is not statistically significant. The authors cannot reject alternative hazard ratios between 0.79 and 1.33. Values below 1 would indicate that using genital talc prevents the development of ovarian cancer.

[39] Women are assigned to "never" or "ever" groups prior to the existence of lawsuits and news related to genital talcum powder use and risks of ovarian cancer.

[40] Only 697 women out of over 40,000 did not provide information to this question, and these women are excluded from the results.

1. Scenario 1 classifies women with missing or non-contradictory survey data at baseline using follow-up genital talc survey data

32. Scenario 1 departs from the baseline analysis in three ways. First, if genital talc use is missing at enrollment, but available at follow-up (at most 2% of the sample),[41] then the woman's genital talc use is taken from the follow-up survey.[42] Second, for participants whose genital talc use is missing at both baseline and follow-up, O'Brien assumes and randomly assigns that 35% were genital talc users and 65% were not.[43] Third, if a woman indicated at enrollment that she was not a genital talc user, but later, at follow-up, stated that she was a genital talc user and the "age reports [are] not contradictory" (8% of the sample and 9% of all ovarian cancer cases),[44] then O'Brien assumes the survey participant was a genital talc user.[45]

33. Scenario 1's three departures from the baseline analysis introduce "recall bias." "Recall bias" reflects the notion that individuals may incorrectly remember past genital talc use due to their updated health status in a systematic way. In particular, by looking for an explanation for current health conditions on the basis of past behavior, ovarian cancer patients are more likely to have been affected by seeing news stories on the topic. Note that this differs from simple recall error that would equally apply to all participants; the recall bias explicitly increases the likelihood that ovarian cancer cases will recall genital talc use compared with non-cases. Therefore, when the authors update the assignment of survey participants from "missing" (based on prospective baseline status) to genital talc user (based on retrospective follow-up status), they introduce recall bias into the sample.

34. "Recall bias" can affect the reliability of the data and results in O'Brien (2024). Indeed, O'Brien (2024) acknowledges that "recall bias" may affect their data: "[i]n studies with retrospective data collection, women with and without ovarian cancer may differentially report exposure, leading to recall bias."[46] Dr. Katie O'Brien also noted this concern in a discussion

[41] O'Brien (2024), Table A5.
[42] O'Brien (2024), Table A5.
[43] O'Brien (2024), Table A5.
[44] O'Brien (2024), Table A5.
[45] O'Brien (2024), Table A5.
[46] O'Brien (2024), p. 2.

about her 2020 *JAMA* article: "for this topic in particular, there is some evidence to suggest that recall bias is really important, especially once the lawsuits started in the early 2010s—that cases [of ovarian cancer] are more likely to report use than non-cases, just because of the timing and being aware that there is this possible connection between genital powder use and ovarian cancer."[47] In other words, Dr. O'Brien agrees that "recall bias" may incorrectly elevate the prevalence of genital talc estimated among women with ovarian cancer, compared with the true prevalence of genital talc use among women with ovarian cancer.

35. Due to this enrichment of the sample with "recall bias," the authors' estimated HR associated with Scenario 1 is 1.07 (95% confidence interval of 0.84–1.35) which is greater than the HR of 1.02 from the baseline analysis.[48] However, despite this "recall bias"-related inflation in the HR, the confidence intervals for the HRs in the baseline analysis and Scenario 1 largely overlap, and the authors' overall conclusion from Scenario 1 remains the same as that for the baseline analysis: using genital talc is not statistically significantly associated with ovarian cancer risk.

2. Scenario 2 arbitrarily assigns 80% of survey respondents who provide contradictory survey responses to be genital talc users

36. Scenario 2 layers on top of Scenario 1 additional "corrections" to the data. Specifically, in Scenario 2, O'Brien (2024) assumes that 80% of women who reported genital talc nonuse during the enrollment survey, but genital talc use during the follow-up survey, were genital talc users.[49] That is, rather than trust survey participants' original survey responses, O'Brien (2024) "corrects" an arbitrary 80% of these participants' answers and reclassifies these women as genital talc users based on retrospective information reported in a follow-up survey over 10 years later and that is contaminated by "recall bias." In addition to the approximately 10% of ovarian

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[47] See Editor-in-Chief of the International Journal of Gynecological Cancer (IJGC) Dr. Pedro Ramirez. (Host). (2020, September 14). Use of Talcum Powder and Risks of Ovarian Cancer with Katie O'Brien [Audio podcast episode]. In IJGC Podcast. BMJ Talk Medicine. https://ijgcbmj.podbean.com/e/use-of-talcum-powder-and-risk-of-ovarian-cancer-with-katie-o-brien-1684257943/ ("Dr. Katie O'Brien Podcast") at timestamp 5:30.

[48] O'Brien (2024), Table 2.

[49] See O'Brien (2024), Table 2 and Table A5.

cancer cases for whom the genital talc use was assumed in Scenario 1, Scenario 2 "corrects" an additional 3% of the sample, including 4% of ovarian cancer cases.[50]

37. Per the authors' own admission, these retrospective "corrections" (that substitute follow-up values for enrollment values) lead to additional bias in the estimation of association between genital talc use and ovarian cancer.[51] Indeed, estimated HR, which increases from 1.02 for the baseline estimate to 1.07 in Scenario 1, increases further to 1.17 in Scenario 2 with a 95% confidence interval of 0.92–1.49.[52] Although the HR is further increased by more "recall bias", the authors' takeaway from Scenario 2 is the same as that in the baseline analysis: genital talc use is not statistically significantly associated with ovarian cancer risk.

3. Scenarios 3 and 4 arbitrarily switch women who said they were genital talc nonusers at baseline to genital talc users in the data

38. Scenario 3 and Scenario 4 build on Scenario 1 and Scenario 2 and introduce additional "corrected" and "imputed" genital talc use among women. Specifically, in these scenarios, the authors "correct" or "impute" the genital talc use of women who indicated they were not genital talc users at the enrollment survey, but who did not provide a response about their genital talc use at the follow-up survey (19% of the sample and 37% of ovarian cancer cases).[53] In Scenario 3, these women are all "corrected" to be genital talc users, and in Scenario 4, whether or not these women are genital talc users is "imputed."[54] As I explain below, Scenario 3 and Scenario 4 generate unreliable and flawed results.

39. Regarding Scenario 3, O'Brien (2024) does not attempt to defend the plausibility of their "corrections" and the HR they ultimately compute. Specifically, the authors state that

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[50] The authors also "correct" 10% of the respondents who indicated "user at enrollment, never user at follow-up" to be nonusers. See O'Brien (2024), Table A5. 80%*3%+10%*7%=3.1%; 80%*5%+10%*2%=4.2%.

[51] Se e.g., Dr. Katie O'Brien Podcast ("[F]or this topic in particular, there is some evidence to suggest that recall bias is really important, especially once the lawsuits started in the early 2010s— that cases are more likely to report use than non-cases, just because of the timing and being aware that there is this possible connection between genital powder use and ovarian cancer").

[52] O'Brien (2024), Table 2.

[53] O'Brien (2024), Table A5.

[54] O'Brien (2024), Table A5.

"[t]ogether, Scenarios 2 and 3 demonstrate the range of results defined by how women in the undefined category are classified, with the true exposure distribution falling somewhere between the two extremes."[55] However, given the recall bias introduced into Scenario 2 that artificially inflates the estimated HR, the statement that Scenario 2 provides a lowest extreme is incorrect (as evidenced by both the baseline analysis and Scenario 1 leading to lower HRs). Regardless, it appears that the authors do not believe Scenario 3 could represent the true association between genital talc use and ovarian cancer.

40. Scenario 4 uses a Multiple Imputation by Chained Equations ("MICE")-based method (explained in more detail below) to "impute" or guess which women—who said they were genital talc nonusers at baseline, but did not provide an answer at the follow-up—were genital talc users.[56] That is, despite the fact that these women only indicated genital talc nonuse, O'Brien (2024) assumes that some were actually genital talc users. O'Brien (2024) provides no justification for this. In fact, in prior work, Dr. O'Brien appears to conclude that such an "imputation" would be unlikely to improve the reliability of the data and results. According to O'Brien (2023), "women could recall whether they ever used certain feminine hygiene products [including genital talc] with good consistency."[57]

41. The authors' rationale for Scenario 3 and Scenario 4 is unclear, particularly considering Dr. O'Brien's prior statements about the consistency of participants' responses regarding genital talc use over time. In O'Brien et al. (2023), when discussing the difference in reported use of genital talc between the enrollment and the follow-up, the authors state that "[w]omen were fairly consistent in their reported use of [genital talc] … Discrepancies in self-reported genital talc use were primarily driven by women who initially reported using during early adolescence, but later reported never using."[58] In other words, discrepancies in reported genital talc use over time tend to be concentrated among respondents who indicated at enrollment that they were genital talc users, but who indicated at follow-up that they were not. It is thus unclear why the authors here assume that misreporting would have been substantial among women who stated

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55 O'Brien (2024), p. 4.

56 O'Brien (2024), p. 4.

57 O'Brien (2023), p. 384.

58 O'Brien (2023), p. 383.

they were nonusers initially but did not reply to the follow-up survey. Doing so is not supported by their own data and is inconsistent with good statistical practice for the handling of missing data.

42. In Scenario 3 and Scenario 4, O'Brien (2024) finds a positive association between genital talc use and ovarian cancer. That is, only when women who never stated that they were genital talc users are reclassified as genital talc users do the authors find a statistically significant positive relationship between genital talc use and ovarian cancer. In the subsections below, I provide further detail on why O'Brien (2024)'s "imputations" of, "corrections" to, and assumptions regarding a woman's genital talc are flawed and unreliable.

B. O'Brien (2024)'s "Imputations" of Genital Talc Use Exacerbate "Recall Bias" in the Authors' Data

43. As described above, in Scenario 4, O'Brien (2024) "imputes" the genital talc use for women who indicated at enrollment that they were not genital talc users, but who did not provide information about genital talc use at follow-up. Specifically, O'Brien (2024) uses the MICE procedure to identify which of these women were likely genital talc users based on their demographic, economic, and health characteristics. However, O'Brien (2024)'s use of this procedure actually exacerbates the "recall bias" about which the authors complain.

44. To illustrate why this is the case, I first describe several key parts of the MICE procedure as applied in O'Brien (2024). While the procedure itself involves several additional steps,[59] at a high level, O'Brien (2024) computes the probability that any particular survey respondent was a genital talc user based on her demographic, economic, and health characteristics. They also include ovarian cancer and non-missing exposure (genital talc use) based on baseline and follow-up time points as auxiliary variables in the prediction model for genital talc use. Unfortunately, the authors do not follow best practices in reporting the exact model used to predict talc exposure status, so it is not possible to get a complete picture of the modeling approach. Most importantly, it is not clear how non-missing genital talc use at each time point is incorporated

[59] See, e.g., M. Azur et al. (2011), "Multiple Imputation by Chained Equations: What Is It and How Does It Work?," *International Journal of Methods in Psychiatric Research* 20(1), pp. 40–49 ("Azur (2011)").

(they could be considered as separate or in some composite combined fashion). It is, however, possible to determine that in building the exposure prediction model, the authors first consider all women for whom genital talc use is not missing (which, in the case of O'Brien (2024), includes all women for whom the genital talc status is assumed or "corrected" as in Table A5). Among these women, the authors estimate a (presumably logistic) regression model that approximates how genital talc ever versus never use varies with the demographic, economic, and health characteristics listed in Table 2. They then input the demographic, economic, and health characteristics of each woman who was a genital talc nonuser at enrollment, but for whom genital talc use is unavailable at follow-up, into the regression model just estimated to compute the probability that each of these women was a genital talc user. As a concrete example, if genital talc use is more common among lower income, white, overweight survey participants and does not vary with other demographic, economic, or health characteristics, then the MICE procedure will assign to lower income, white, overweight women without data on genital talc use a higher probability of genital talc use. Note that in the MICE procedure, the above steps are extended to iterate over all variables that have missing data, i.e., each variable with missing data has their missing data predicted in turn, though O'Brien does not state which of the variables are "imputed" with MICE. (The authors do, however, state that they remove all data where key covariates are missing,[60] but unfortunately, they do not specify which covariates are the key covariates.) The final model (here, Cox proportional hazards) is then fitted to the completed dataset, and this is recorded as "imputed" model 1. The whole process is repeated multiple times to generate multiple "imputations" of each missing variable and then the results are combined in a form of averaging such as those suggested by "Rubin's rules" mentioned in O'Brien (2024).[61]

45. The "imputation" method described above introduces additional "recall bias" into O'Brien (2024)'s estimates beyond that introduced by the authors' other scenarios. Because the data used to estimate the regression model that approximates how genital talc use varies with demographic, economic, and health characteristics is computed using data that is itself contaminated by recall bias (observed genital talc use status at both timepoints), any imputed

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[60] See O'Brien (2024), p. 4.

[61] O'Brien (2024), p. 4.

probabilities derived from that regression model are similarly contaminated. That is, O'Brien (2024) computes likelihoods of genital talc use for the 19% of the sample (and 37% of the ovarian cancer cases) that are affected by the very "recall bias" about which they complain.[62] As a consequence, O'Brien (2024)'s "imputation" approach may "impute" genital talc users simply because they have characteristics similar to that of other participants who displayed "recall bias," increasing the degree to which "recall bias" introduces error regarding genital talc use into the sample and results.

46. In addition to the "recall bias" being carried through the prediction process as described above, the problem is compounded by the "correction" step prior to "imputation" as introduced in Scenario 2;[63] that "correction" step has its own "recall bias" component. The "recall biased" data generated by the "correction" process are assumed to be correct when used as data for fitting "imputation" models. Therefore, this additional "recall bias" from the "corrected" data is also added onto the "recall bias" from the MICE prediction process described above.

47. An additional concern here is that for O'Brien (2024)'s "imputation" procedure to be reliable, women missing genital talc information at follow-up would need to overlap with all other women in the sample along the demographic, economic, and health dimensions used to predict genital talc use. This, however, is clearly not the case in the Sister Study data, as the authors themselves note. Specifically, "women with incident cancer were overrepresented in this…group," which comprised 19% of all women in the study, but 37% of all ovarian cancer cases in the study.[64] Put differently, O'Brien (2024) predicts exposure for a group of participants using data from fundamentally different participants and their demographic, economic, and health characteristics may not capture these differences. There is a clear difference in the nature of the data that were missing. As a result, study participants' "imputed" genital talc use—and any resulting estimates of the association between genital talc use and ovarian cancer in O'Brien (2024)—are heavily reliant on the form and assumptions of the imputation model that is extrapolated to apply to the new and different participants.

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[62] O'Brien (2024), Table A5.

[63] See Section IV of this report; O'Brien (2024), p. 4, Table A5.

[64] O'Brien (2024), p. 3; O'Brien (2024) Table A5.

C. O'Brien (2024)'s Chosen Imputation Method Is Inappropriate for the Dataset That the Authors Use

48. O'Brien (2024) implements the MICE procedure which requires that certain assumptions be true in order for the method to generate valid imputations. One such requirement is that the data on genital talc use among survey respondents must not be "missing not at random" ("MNAR").[65] In this subsection, I explain what it means for data to be MNAR and then highlight that the genital talc use data in the Sister Study are MNAR, which renders the authors' results unreliable.

49. When (survey) data are missing, the missingness may be characterized as "missing completely at random" ("MCAR"), "missing at random" ("MAR"), or MNAR.

- Survey data are MCAR if the likelihood that any particular data point is missing is uniform across the dataset. In other words, if survey participants accidentally skip a question in a way that is unrelated to their characteristics or their answer to the question, the resulting data would be MCAR.
- Survey data are MAR when the likelihood that a particular datapoint is missing is related to other observed data about the survey respondent (but importantly not to the missing data itself). In other words, datapoints are systematically missing, but in a way that can be accounted for by using the observed data.[66] For example, if younger adults are less likely to respond to survey questions about income (and age is observed), then those data would be MAR.
- Survey data are MNAR when the likelihood of a datapoint being missing is related to the true value of the datapoint. In other words, data about a variable are missing in a way that is related to that missing data. To continue the example above, if lower-income individuals are less likely to respond to survey questions about income, then those data would be MNAR, since the probability of missingness is directly related to the datapoint value (i.e., the respondent's income).

While several methods exist to deal with MCAR (e.g., pointwise deletion) and MAR data (e.g., MICE), data that are MNAR are particularly challenging to work with in a reliable manner, typically requiring difficult-to-justify assumptions.

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[65] See, e.g., Azur (2011), p. 41.

[66] That is, if we can perfectly correct for the observed data, then the leftover unexplained part can be thought of as MCAR.

50. Here, data on genital talc use are MNAR because "women with incident cancer were overrepresented in this…group [with missing data],"[67] and therefore, are inappropriate for the "imputation" procedure that O'Brien (2024) employs. It is clear that the probability of missingness of genital talc use at the follow-up time point depends on whether or not a participant used genital talc. This is related to the previously described "recall bias" in that missingness will likely be lower among cases that have an interest in reporting their genital talc use status but could also be affected by any associated stigma in reporting genital talc use after the "surge in talc-related lawsuits and media coverage."[68]

51. Extensions exist that can be applied to the MICE approach to try and deal with MNAR data; in particular, the not-at-random fully conditional specification (NARFCS) procedure.[69] However, there is no indication that O'Brien (2024) underwent such an exercise. These require the specification of new "sensitivity" parameters that relate to the extent of the not-at-random structure in the data. These sensitivity parameters are not fully estimable, and the idea is to vary these parameters and evaluate how results are affected. One approach in particular is to examine whether there is a "tipping point" in the conclusions, where changing the sensitivity parameter(s) leads to different evaluation of the results (e.g., statistical significance vs. not). The value of the tipping point is then assessed by experts in the field to determine whether the maximum level of nonrandom missingness for the overall conclusions to be accepted is within plausible ranges. In essence, this complex approach is the best that can be achieved because there is no way around the fact that results depend on the level of the nonrandom component in MNAR models unless the nonrandom mechanism is known (which is rarely the case).

D. O'Brien (2024)'s "Imputed" Genital Talc Use Is Likely a Poor Proxy for a Woman's Actual Genital Talc Use

52. Even assuming that the multiple imputation method that O'Brien (2024) uses is valid in this setting, which it is not, the accuracy of the "imputed" genital talc use is likely poor. As

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[67] O'Brien (2024), p. 3.

[68] O'Brien (2020), p. 50.

[69] Tompsett D.M., Leacy F., Moreno-Betancur M., Heron J., White I.R. On the Use of the Not-at-Random Fully Conditional Specification (NARFCS) Procedure in Practice. *Statistics in Medicine*. 2018 Jul 10;37(15):2338-53.

described above, the MICE method that is employed by O'Brien (2024) relies on demographic, economic, and health characteristics to predict genital talc use. To the extent that these demographic, economic, and health characteristics are poor predictors of actual genital talc use, then any resulting "imputed" genital talc use values are similarly poor proxies for actual genital talc use.

53. As an initial matter, O'Brien (2024) provides no indication of the strength and predictive ability of their imputation method. Consistent with best practices, the authors could have provided a statistical measure of how well their execution of the MICE method performs "in sample," that is, within the existing data for which genital talc use is known. To the extent that the authors' approximation from MICE gives a poor prediction of the genital talc use of women who are not missing data, then the "imputations" based on this model for missing data are also likely to be poor proxies for actual genital talc use. Even if the "imputation" is adequate in-sample, i.e., within the non-missing sample, any results would still need to be taken with caution because there appears to be a systematic difference in the missing vs. observed data.[70]

54. Indications from other work by O'Brien, specifically Chang (2024), cast doubt on the ability of the demographic, economic, and health characteristics used in O'Brien (2024) to accurately predict actual genital talc use. In Chang (2024), using the Sister Study, the authors investigate the correlation between genital talc use and each of several demographic, economic, and health characteristics.[71] A correlation of 1.00 would mean that genital talc use and the studied characteristic are perfectly correlated and the characteristic would be an ideal predictor, whereas a correlation of 0.00 means that genital talc use is uncorrelated to the studied characteristic, making the studied characteristic a useless predictor of genital talc use. The authors find that genital talc use is uncorrelated or poorly correlated with each of the demographic, economic, or health characteristics they assess.[72] Below, I list several of the correlations between genital talc use and demographic, economic, or health characteristics used in O'Brien (2024) that the authors of Chang (2024) compute:

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[70] See, e.g., Section VI.B of this report.

[71] See Chang (2024), Figure 2, Online Appendix, Table S3.

[72] See Chang (2024), Figure 2, Online Appendix, Table S3.

a. Age at Enrollment: –0.01

b. Hispanic, non-Black race: 0.00

c. Income: –0.06

d. Urban: -0.01

e. Education: –0.05

In fact, the authors of Chang (2024) find that only one demographic, economic, or health characteristic demonstrates correlation with genital talc use with a coefficient greater than 0.10 (body mass index) and even that characteristic is poorly correlated with genital talc use (correlation coefficient of 0.13).

55. In sum, available evidence renders it likely that O'Brien (2024)'s "imputed" genital talc use—computed based on demographic, economic, and health characteristics that are uncorrelated with genital talc use—are likely poor proxies for study participants' actual genital talc use.

E. O'Brien (2024) Relies on Circular Logic to "Impute" Genital Talc Use

56. In their "imputation" model, O'Brien (2024) uses ovarian cancer status (among other demographic, economic, and health variables) to "impute" whether a woman was a genital talc user.[73] In the context of their "imputation" model, for a woman who reported at enrollment that she did not use genital talc, but who provided no data on genital talc use at follow-up, the authors "impute" whether or not the woman was indeed a genital talc user based on whether or not she has ovarian cancer. O'Brien (2024) then uses this "imputed" genital talc use to estimate an association with ovarian cancer. Below, I explain why this circular relationship may lead to flawed and unreliable findings.

57. This circularity between ovarian cancer and genital talc use may artificially reinforce the authors' finding of an association between genital talc use and ovarian cancer. To the extent that genital talc use is more prevalent among ovarian cancer cases than among the remainder of the population, as O'Brien (2024) claims, along with the "recall bias," this generates a feedback loop between genital talc use and ovarian cancer. In the authors' setup, greater ovarian cancer incidence "imputes" greater genital talc use. This, in turn, generates a larger HR that can lead to

[73] O'Brien (2024), Table 2.

the flawed conclusion that greater genital talc use is mechanically related to greater ovarian cancer incidence. Put differently, ovarian cancer incidence feeds back on itself to prop up the authors' estimated association between ovarian cancer and genital talc use.

58. O'Brien (2024) does not demonstrate whether their findings are robust to the inclusion of ovarian cancer status as a predictor of genital talc use. In light of this circularity, the authors should have tested whether their findings were robust to excluding ovarian cancer status from their prediction model. However, the authors have not done so, rendering their conclusions unverifiable.

F. "Imputed," "Corrected," or Assumed Data Comprise an Unreliably Large Share of O'Brien (2024)'s Data on Genital Talc Use

59. While the criticisms I describe above each lead O'Brien (2024) to compute HRs that are flawed, unreliable, and generally biased upward, the sheer number of women for whom genital talc use is "imputed," "corrected," or assumed exacerbates these problems. While the precise fraction of the sample that is subject to "imputation," "correction," or assumption varies across their scenarios, in the authors' preferred specification, Scenario 4, this fraction represents a total of 38% of women and 54% of ovarian cancer cases. Below, I briefly highlight how the authors' decisions regarding "imputation," "correction," and assumption led them to speculate about the genital talc use for this fraction of women and ovarian cancer cases.

a. The authors classify women who are genital talc nonusers at enrollment, but for whom genital talc use at follow-up is missing, as "eligible for imputation." Per the authors' calculations, this comprises 19% of women in the survey and 37% of ovarian cancer cases.[74]

b. The authors classify women who indicated genital talc use at either enrollment or follow-up survey, but genital talc nonuse at the other, as "eligible for correction." Per the authors' calculations, this comprises 10% of women in the survey and 7% of ovarian cancer cases.[75]

[74] O'Brien (2024), Table A5.

[75] O'Brien (2024), Table A5.

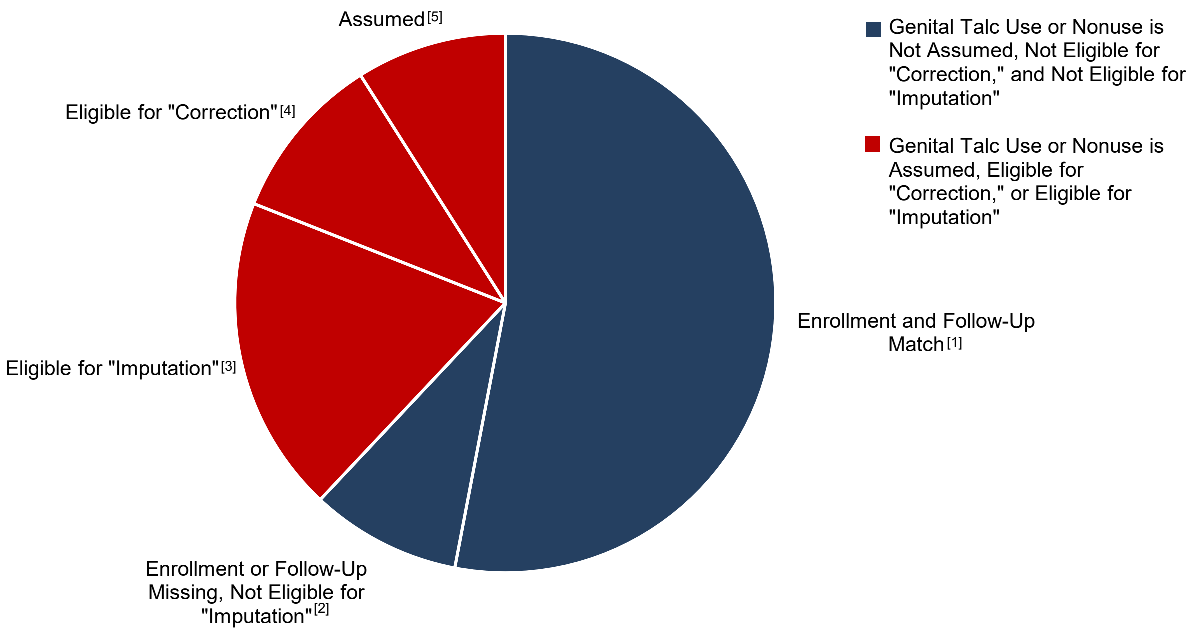
c. The authors assume that women who indicated genital talc nonuse at enrollment, but genital talc use at follow-up are genital talc users, despite their differing responses and susceptibility to recall bias at follow-up. Per the authors' calculations, this comprises 9% of women in the survey and 10% of ovarian cancer cases.[76]

60. Put differently, the genital talc use for nearly 40% of women in the Sister Study sample and the majority of women in the sample with ovarian cancer are not based on actual data, but rather are based on the authors' flawed conjectures. The fact that the key variable of interest—genital talc use—is generated in this flawed manner for so large a share of the sample leads to uncertainty and unreliability in the authors' findings.

[76] O'Brien (2024), Table A5. While a history of genital talc nonuse at enrollment and a history of genital talc use at follow-up do not necessarily contradict one another due to the differing time periods covered by the questions, the authors assume that the response at follow-up is accurate.

Exhibit 2

Misclassification of Genital Talc Use in Scenario 4 — All Participants



Source: O'Brien (2024), Table A5

Note:

[1] This category includes participants whose self-reported genital talc use or nonuse was the same at both enrollment and follow-up. These participants are found in rows 1, 6, and 7 in Table A5 of O'Brien (2024).

[2] This category includes participants whose self-reported genital talc use or nonuse was missing at either enrollment or follow-up but for whom genital talc use is not eligible for "imputation." These participants are found in rows 8, 9, 10, and 11 in Table A5 of O'Brien (2024).

[3] This category includes participants who self-reported as genital talc nonusers at enrollment but for whom there was no follow-up response. These participants are found in row 4 in Table A5 of O'Brien (2024).

[4] This category includes participants whose self-reported gential talc use was inconsistent across enrollment and follow-up. These participants are found in rows 2 and 5 in Table A5 of O'Brien (2024).

[5] This category includes participants who self-reported as genital talc nonusers at enrollment but self-reported as genital talc users at follow-up without contradictory age information and participants who are missing both the enrollment and follow-up response. These participants are found in row 3 and 12 in Table A5 of O'Brien (2024).

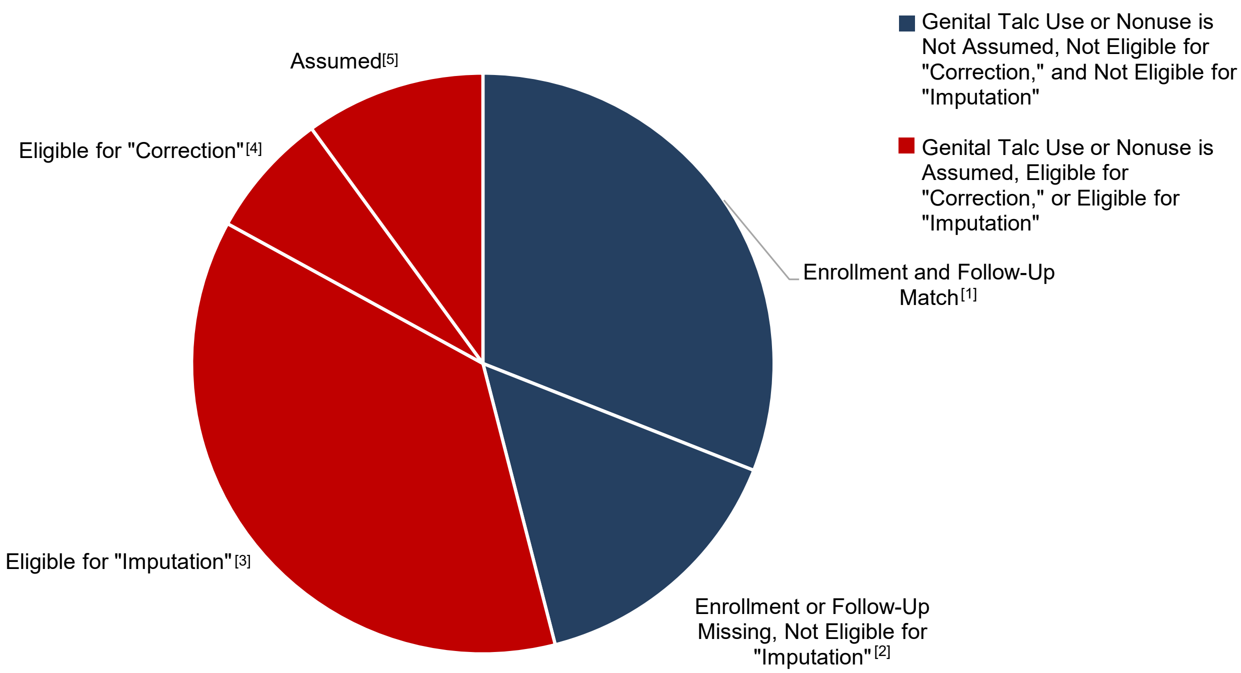
61. Per the authors' calculations, O'Brien (2024)'s methodology generates significant uncertainty in the estimate of the fraction of women in the Sister Study sample who are genital talc users. As a result of their "imputations," "corrections," and assumptions, O'Brien (2024) observes that the fraction of women who they deem to have used genital talc can be as low as 28% and as high as 56%, depending on the scenario they choose.[77] This large range further underscores the uncertainty inherent in and unreliability of their "imputations," "corrections,"

[77] O'Brien (2024), Table 2 and Table A2.

and assumptions. As a result, any resulting estimates of the association between genital talc use and ovarian cancer are similarly flawed and unreliable.

Exhibit 3

Misclassification of Genital Talc Exposure in Scenario 4 — Participants with Ovarian Cancer



Source: O'Brien (2024), Table A5

Note:

[1] This category includes participants whose self-reported genital talc use or nonuse was the same at both enrollment and follow-up. These participants are found in rows 1, 6, and 7 in Table A5 of O'Brien (2024).

[2] This category includes participants whose self-reported genital talc use or nonuse was missing at either enrollment or follow-up but for whom genital talc use is not eligible for "imputation." These participants are found in rows 8, 9, 10, and 11 in Table A5 of O'Brien (2024).

[3] This category includes participants who self-reported as genital talc nonusers at enrollment but for whom there was no follow-up response. These participants are found in row 4 in Table A5 of O'Brien (2024).

[4] This category includes participants whose self-reported gential talc use was inconsistent across enrollment and follow-up. These participants are found in rows 2 and 5 in Table A5 of O'Brien (2024).

[5] This category includes participants who self-reported as genital talc nonusers at enrollment but self-reported as genital talc users at follow-up without contradictory age information and participants who are missing both the enrollment and follow-up response. These participants are found in row 3 and 12 in Table A5 of O'Brien (2024).

G. Inconsistencies in the Sister Study Survey Questionnaires Compound the Flaws and Unreliability of the Authors' "Imputed," "Corrected," or Assumed Genital Talc Use Data

62. As I described in Section IV, the Sister Study asked respondents different questions regarding genital talc use at enrollment (2003–2009) and follow-up (2017–2019). These

differences in the Sister Study survey questionnaires introduce additional flaws and unreliability into the authors' "imputed," "corrected," or assumed genital talc use data.

63. First, the Sister Study questionnaires differ in the responses they allow participants to select. In the enrollment survey, when asked about genital talc use during ages 10–13, respondents were offered four choices: "Did not use;" "Sometimes;" "Frequently;" and "Don't know."[78] At follow-up, when asked whether they ever used genital talc, respondents could only indicate "yes" or "no," but could not indicate that they did not know.[79] In other words, at follow-up, respondents were asked about genital talc use from several years, if not several decades, prior, but could not indicate that they did not know the answer or were uncertain. Instead, they were required to select "yes" or "no"—or skip the question entirely. Thus, with respect to those respondents who (a) said they did not use genital talc in response to the enrollment survey and (b) did not answer the question regarding genital talc use in the follow-up survey, there is no rational basis for the authors to have assumed that these women used genital talc (the opposite of their reported use) as a premise of their analysis.

64. Second, the Sister Study questionnaires differ in the time period over which they ask respondents about their genital talc use. In the enrollment survey, respondents were asked about genital talc use between the ages of 10–13 and during the 12 months prior to completing the survey.[80] In the follow-up survey, respondents were instead asked whether they were ever a genital talc user.[81] A respondent who answered at enrollment that they were at some point in time a genital talc user, but who answered at follow-up that they were never a genital talc user generated contradictory responses. While the authors claim to "correct" these individuals' contradictory responses, their "corrections" are arbitrary and unreliable.

65. As described previously, O'Brien (2024) "imputes," "corrects," or assumes the genital talc use based on survey participants' responses to both the enrollment and follow-up questionnaires. To the extent that inconsistencies in the Sister Study questionnaire generated flawed or unreliable data about participants' genital talc use at either enrollment or follow-up,

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78 Enrollment Questionnaire, p. 10.

79 Follow-Up Questionnaire, p. C-13.

80 Enrollment Questionnaire, p. 10.

81 Follow-Up Questionnaire, p. C-13.

the authors' "imputed," "corrected," or assumed genital talc use data inherit these flaws and unreliability.

VII. O'BRIEN (2024)'S ESTIMATED HAZARD RATIOS ARE INFLATED AND NOT ROBUST

66. In the prior section, I explained how O'Brien (2024)'s "imputations" of, "corrections" to, and assumptions regarding Sister Study participants' genital talc use generate flaws and unreliability in the authors' analysis. Here, I explain the implications of these "imputations," "corrections" and assumptions for the magnitude and accuracy of their estimated hazard ratios. Specifically, as a result of these "imputations," "corrections," and assumptions, O'Brien (2024) estimates associations between genital talc use and ovarian cancer that are inflated, unstable, and sensitive to minimal perturbations in the authors' classification of genital talc use and nonuse.

A. O'Brien (2024)'s Estimated Hazard Ratios Are Inflated

67. O'Brien (2024) makes several "imputations," "corrections," or assumptions that classify women as genital talc users or nonusers in a way that biases upward the authors' estimated HRs and inflates their estimate of the association between genital talc use and ovarian cancer.

68. To begin, O'Brien (2024)'s "imputations" of and "corrections" to genital talc use among women result in a greater share of ovarian cancer cases among genital talc users in the data the authors use to estimate their HRs:

a. O'Brien (2024) considers women who stated that they were not genital talc users at enrollment, but who did not provide information about genital talc use at follow-up, to be "eligible for imputation."[82] In other words, even though the authors observe in the data that these women were genital talc nonusers, but never observe in the data that these women ever used genital talc, O'Brien (2024) "imputes" that some (unspecified) fraction were genital talc users.[83] According to O'Brien (2024),

[82] O'Brien (2024), Table A5.

[83] O'Brien (2024), Table A5.

"women with incident cancer were overrepresented in this undefined group."[84] Specifically, this group comprises 19% of respondents, but 37% of ovarian cancer cases.[85] To the extent that any of these participants are not actually genital talc users—which would be consistent with the only actual data on these women—when O'Brien (2024) "imputes" that some were genital talc users, the authors add a disproportionate share of ovarian cancer cases to the group of genital talc users. Therefore, they inflate the estimate of the association between genital talc use and ovarian cancer.

b. O'Brien (2024) considers women who indicated at enrollment that they were genital talc nonusers, but who indicated at follow-up that they were genital talc users (and their reported ages of use were irreconcilable with stating nonuse in the enrollment survey), as "eligible for correction."[86] Despite the prospective indication of these women that they were not genital talc users and the authors' inability to evaluate and validate whether "recall bias" affected their follow-up responses, the authors arbitrarily classify a large fraction (80%) as genital talc users.[87] According to O'Brien (2024), this group comprises 3% of respondents, but 5% of ovarian cancer cases, meaning that it overrepresents ovarian cancer cases compared to the remainder of the sample.[88] To the extent that any of these participants are not actually genital talc users, when O'Brien (2024) "corrects" the genital talc use of these women, the authors add a disproportionate share of ovarian cancer cases to the group of genital talc users. Therefore, they inflate the estimate of the association between genital talc use and ovarian cancer.

c. O'Brien (2024) also considers women who indicated they were genital talc users at enrollment, but genital talc nonusers at follow-up, as "eligible for correction."[89]

[84] O'Brien (2024), p. 3.
[85] O'Brien (2024), Table A5.
[86] O'Brien (2024), Table A5.
[87] O'Brien (2024), Table A5.
[88] O'Brien (2024), Table A5.
[89] O'Brien (2024), Table A5.

Despite their prospective indication that they were genital talc users, O'Brien (2024) "corrects" 10% of such women to be genital talc nonusers.[90] According to O'Brien (2024), this group is underrepresented among ovarian cancer cases because it comprises 7% of respondents, but 2% of ovarian cancer cases.[91] To the extent that any of these participants were genital talc users, when O'Brien (2024) "corrects" the genital talc use of these women, the authors subtract a disproportionately small fraction of ovarian cancer cases relative to non-cases from the group of genital talc users. As a result, the share of ovarian cancer cases among the group of genital talc users is now larger and this causes the authors to inflate their estimate of the association between genital talc use and ovarian cancer.

69. In addition, O'Brien (2024) treats participants' responses regarding genital talc use asymmetrically and in a way that biases upward the estimated association between genital talc use and ovarian cancer. As an example, consider the authors' treatment of women in the Sister Study who provide no data about genital talc use at follow-up. On the one hand, if a woman indicates that she was a genital talc user at the enrollment survey, then O'Brien (2024) always assumes the woman is a genital talc user.[92] On the other hand, if a woman indicates that she was not a genital talc user at the enrollment survey, then O'Brien (2024) assumes that at least some of these women were genital talc users (100% in Scenario 3, and some "imputed" fraction in Scenario 4). Following the same logic as in the prior paragraph, because these women are overrepresented among ovarian cancer cases, the authors' "imputation" that some of these women are genital talc users increases the share of genital talc users with ovarian cancer cases and inflates the association between genital talc use and ovarian cancer compared to if O'Brien (2024) had simply used the survey participants' actual answers (as the authors do for women who indicated genital talc use at enrollment).

[90] O'Brien (2024), Table A5.
[91] O'Brien (2024), Table A5.
[92] O'Brien (2024), Table A5.

B. O'Brien (2024)'s Results Are Unstable and Sensitive to Minimal Perturbations in "Imputation" of, "Correction" to, or Assumptions Regarding Genital Talc Use

70. If O'Brien (2024)'s results were reliable, then they should be robust to minor modifications to the authors' implemented procedures, such as the number of observations "imputed" or "corrected" or potential alternative specifications. To the contrary, O'Brien (2024)'s own results demonstrate that their finding of a positive and statistically significant association between genital talc use and ovarian cancer is sensitive to the classification of only a few observations.

71. O'Brien (2024), Figure 2 demonstrates that the authors' results can be considerably changed by changing the genital talc use of only a small number of observations.

a. O'Brien (2024), Figure 2, Panel B shows that the authors' results hinge on as few as six out of over 40,000 women (or 0.015% of the sample). Had the authors "imputed" or "corrected" the genital talc use of six fewer women, as they do in one of these scenarios, they would not have detected a statistically significant association between genital talc use and ovarian cancer. The likelihood of such a misclassification error is not insignificant since the authors "impute," "correct," or assume the genital talc use of 158 women with ovarian cancer (54% of 292 ovarian cancer cases); if the authors guessed incorrectly that six of these women were genital talc users—which is a possibility since they never indicated genital talc use—then their finding of a positive association between genital talc use and ovarian cancer would no longer hold. Note that this sensitivity is even more acute than it first appears because it involves switching participants who may or may not be genital talc users at follow-up due to "recall bias." If *only* individuals truly influenced by "recall bias" are switched (which may be a smaller subset than six), then the reductions in hazard ratio will be expected to be larger.

b. O'Brien (2024), Figure 2, Panel A demonstrates that the authors' results are highly sensitive to their assumptions regarding the extent of the "recall bias." If 50% of the ovarian cancer cases have "recall bias," then the authors' "correction" leads to a HR of 1.07 with a 95% confidence interval of 0.81–1.40, which is not statistically significantly different from zero. If 67 cases were due to "recall bias" then the

authors would conclude there is actually a statistically significant relationship between genital talc use in favor of ovarian cancer protection.[93] Given that there is no way to validate what the proportion of "recall bias" actually is or estimate it reliably, this makes the "recall bias" modeling "correction" an exercise in futility. However, what we can say is that Figure 2 implies that reasonable expectations of what the recall bias levels could be, i.e., combinations of the effects in Panels A and B, would easily wipe out any statistically significant results.

VIII. O'BRIEN (2024)'S "RECALL BIAS"-CORRECTED ESTIMATES OF THE ASSOCIATION BETWEEN GENITAL TALC USE AND OVARIAN CANCER ARE FLAWED AND UNRELIABLE

72. O'Brien (2024) purports to have "investigated the potential impact of recall bias on the association between genital talc use and ovarian cancer."[94] To do so, the authors implement Scenario 4 described above and then layer on top of that three potential assumptions regarding how recall bias may have affected survey responses:

a. The authors recode a proportion (10–90%) of ovarian cancer cases classified as genital talc users to be nonusers.

b. The authors recode a proportion (10–90%) of ovarian cancer cases classified as nonfrequent and short-term genital talc users to be nonusers.

c. The authors recode a proportion (5–25%) of individuals without ovarian cancer to be infrequent or short-term genital talc users.[95]

As I explain below, O'Brien (2024)'s analysis of how recall bias affects their estimate of the association between genital talc use and ovarian cancer is flawed and unreliable.

73. To begin, O'Brien (2024) purports to assess the alleged "recall bias" under only a very narrow and specific set of assumptions. In particular, O'Brien (2024) assesses "recall bias" using Scenario 4, which is premised on data that is "corrected" or "imputed" without basis or

[93] O'Brien (2024), Figure 2.

[94] O'Brien (2024), p. 4.

[95] O'Brien (2024), p. 4.

using unreliable and arbitrary assumptions regarding how "recall bias" may have affected participants. O'Brien (2024) does not assess the alleged "recall bias" under any other set of circumstances. Similarly, O'Brien (2024) only assesses "recall bias" under each of their three potential assumptions separately. That is, the authors fail to consider that "recall bias" may simultaneously affect survey participants' responses in more than one way. These failures render unreliable the authors' conclusions regarding how "recall bias" affects the association between genital talc use and ovarian cancer.

74. In addition, O'Brien (2024) overstates the conclusions they can draw from their contrived exercise. While the authors claim that "correction for [recall bias] error still resulted in HRs above 1.0," they only show this for the specific set of arbitrary and unjustified assumptions described above and a specific fraction of recoded study participants' genital talc use.[96] O'Brien (2024) ignores that, even under Scenario 4, their own results depend on the share of users that they recode. Specifically, recoding a greater share of users in their analysis (which would be a reasonable expectation in the absence of validated estimates) decreases the HR to one (or, in some cases, less than one meaning that genital talc use is statistically significantly associated with ovarian cancer protection).[97] Put differently, the authors' own analysis of "recall bias" leads to a vacuous conclusion: genital talc use may be positively, negatively, or not associated with ovarian cancer.

75. Finally, O'Brien (2024) fails to reconcile their rationale for "recall bias" with the fact that a large share of respondents provided no data on genital talc use at follow-up. According to O'Brien (2024), "recall bias" should increase the likelihood that a participant reports using genital talc at follow-up.[98] However, O'Brien (2024) does not explain how this is consistent with the large fraction of survey respondents (28%) not providing such information at follow-up (as compared to approximately 1% at the baseline evaluation).[99] Since this 28% of respondents

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[96] O'Brien (2024), p. 1.

[97] O'Brien (2024), Figure 2.

[98] O'Brien (2024), p. 2.

[99] In addition, Sister Study participants could ask someone else (e.g., a relative, a friend) to assist with completing the questionnaire or to complete the questionnaire on their behalf. See Follow-Up Questionnaire at p. A-1. It stands to reason that increased opportunities to complete the questionnaire should decrease, rather than increase, the number of Sister Study participants who do not complete the follow-up questionnaire.

comprises 53% of ovarian cancer cases,[100] simply assuming or "imputing" that they were genital talc users causes O'Brien (2024) to overstate the association between genital talc use and ovarian cancer.

76. In sum, O'Brien (2024)'s attempts to account for alleged "recall bias" when they estimate the association between genital talc use and ovarian cancer is flawed and unreliable.

IX. THE LACK OF A PRE-SPECIFIED ANALYSIS PLAN RENDERS THE AUTHORS' CONCLUSIONS FLAWED AND UNRELIABLE

77. When a researcher is comparing multiple outcomes and using multiple modeling approaches, best practice dictates that they should use a pre-specified analysis plan.[101] This pre-specified analysis plan should, for example, lay out the statistics that the researchers plan to estimate, the ways in the which they anticipate processing the data, and the comparisons that they will make. O'Brien (2024) clearly does not follow the best practice. The authors report many analyses, some of which are premised on choices that appear arbitrary and then focus on the isolated outcome of ovarian cancer. This raises the potential that the data may have been "over-fished" for results or is the result of a spurious outcome.

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[100] O'Brien (2024), Table A5.

[101] In my Biostatistical consulting role, I regularly advise clients that they need to consider the issue of multiple comparisons when interpreting their results. I do not advocate for the blind application of multiple comparison corrections, which would generally be ill-advised in a complex inter-related analysis such as this one. However, I do advise that isolated *p*-values less than 0.05 that do not match the general pattern of results will lack biological plausibility. This is such a regular concern that we have an area on our consulting unit website that discusses the issue and points to references. See Common Biostatistical Problems and the Best Practices that Prevent Them, Problem 6. Overuse Of Multiple Comparisons Adjustments. UCSF, available at https://wiki.library.ucsf.edu/display/BIOSTAT/Common+Biostatistical+Problems+and+the+Best+Practices+that+Prevent+Them#CommonBiostatisticalProblemsandtheBestPracticesthatPreventThem. One way we have handled these issues in in our grant proposals. "Although this Aim involves many different measures, we do not plan formal adjustments for multiple comparisons. This is because we expect many measures to show statistically significant differences, and that directions and magnitudes of differences (perhaps including some with p>0.05) will fit a biologically coherent pattern. In this case, each result will reinforce the other, rather than detracting from one another as required by formal multiple comparisons adjustments such as the Bonferroni method. Conversely, if only one or a very few measures reach statistical significance and their directions and/or magnitudes do not coherently fit with << our substantive theory >>, then we will note that the result(s) with p<0.05 lack biological plausibility and could be due to chance despite meeting the conventional cutoff for statistical significance." In my biostatistical consulting role, we recommend researchers use a pre-specified plan.

78. This high risk of a spurious outcome is further compounded by three problems that introduce "recall bias" in favor of the spurious results, 1) the erroneous multiple imputation procedure (erroneous because it assumes that the participants with missing exposure data have the same distribution as the participants with non-missing exposure data–which is clearly untrue because the ovarian cancer rates are much higher in the missing exposure participants); this problem is most acute for ovarian cancer (of all the different cancers considered in the paper) because much more data needs to be imputed in this case, 2) the arbitrary and ill-justified contradictory data correction approach, and 3) the arbitrary and ill-justified recall-bias correction procedures.

Executed this 28th of May, 2024

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John Kornak, Ph.D.

Appendix A

Prepared: May 27, 2024

University of California, San Francisco

CURRICULUM VITAE

Name: John Kornak, PhD

Position: Professor In Residence, Step 3
Epidemiology & Biostatistics
School of Medicine

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EDUCATION

1990 - 1991	Aristotle University of Thessaloniki, Greece	Diploma	Modern Greek Language
1993 - 1996	University of Nottingham, UK	B.Sc.	Mathematics with Statistics
1996 - 2000	University of Nottingham, UK	Ph.D.	Statistics

LICENSES, CERTIFICATION

1999	Gradstat accreditation with the Royal Statistical Society

PRINCIPAL POSITIONS HELD

1999 - 1999	Part-time Lecturer	University of Nottingham, UK	Engineering
2000 - 2000	Post-Doctoral Fellow	MRC Institute of Hearing Research, UK	
2000 - 2002	Post-Doctoral Researcher	University of California, San Francisco	Radiology
2002 - 2003	Post-Doctoral Researcher	The Ohio State University	Statistics
2003 - 2003	Senior Research Statistician	Northern California Institute for Research and Education	

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Prepared: May 27, 2024

2003 - 2006	Assistant Adjunct Professor	University of California, San Francisco	Radiology
2006 - 2010	Assistant Professor In Residence	University of California, San Francisco	Radiology and Biomedical Imaging
2010 - 2016	Associate Professor In Residence	University of California, San Francisco	Epidemiology and Biostatistics
2016 - present	Professor In Residence	University of California, San Francisco	Epidemiology and Biostatistics

OTHER POSITIONS HELD CONCURRENTLY

2003 - 2006	University of California, San Francisco	Assistant Adjunct Professor	Epidemiology and Biostatistics
2006 - 2010	University of California, San Francisco	Assistant Professor In Residence	Epidemiology and Biostatistics
2006 - 2010	University of California, San Francisco	Director of Biostatistics Consulting Service	Radiology and Biomedical Imaging
2009 - present	University of California, San Francisco	Biostatistics Faculty Consultant	CTSI Consulting Service
2014 - present	University of California, San Francisco	Director of Biostatistics Consulting Unit	CTSI Consulting Service
2017 - present	Lawrence Livermore National Laboratories	Visiting Scholar	
2019 - present	University of California, San Francisco	Head of Health Data Science Master's/Certificate Program	Epidemiology and Biostatistics

HONORS AND AWARDS

1997	Travel and registration award	Case Studies in Bayesian Statistics Workshop IV, Carnegie Mellon University, Pittsburgh, PA
1998	Invited attendee (with travel grant award) - Summer School on Markov Chain Monte Carlo Simulation, Rebild, Denmark	Highly Structured Stochastic Systems

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1999	Travel and registration grant award - Second European Conference on Highly Structured, Stochastic Systems Conference, Pavia, Italy	Highly Structured Stochastic Systems
1998	Elected Fellow	The Royal Statistical Society, UK
2003	Travel and registration award	International Workshop on Bayesian Data Analysis, University of California, Santa Cruz
2006	Travel grant award	UCSF Academic Senate
2006	Elected Vice President for Biostatistics of the Bay Area Chapter	The American Statistical Association
2007	Travel grant award	UCSF Academic Senate
2007	President-Elect for the Bay Area Chapter	The American Statistical Association
2008	President of the Bay Area Chapter	The American Statistical Association
2009	Past-President of the Bay Area Chapter	The American Statistical Association
2009	Consultant of the Year - Consistent Excellence Award	UCSF, CTSI
2010	Consultant of the Year - Impact Award	UCSF, CTSI
2010	Elected Council of Chapters Representative	The American Statistical Association
2011	Consultant of the Year - Excellence Award	UCSF, CTSI
2014	Elected Chair of Statistics in Imaging Section for 2016	The American Statistical Association
2024	Selected as Fellow of the American Statistical Association	The American Statistical Association

KEYWORDS/AREAS OF INTEREST

Bayesian decision analysis, Bayesian image analysis, Bayesian image analysis in Fourier space, Bayesian statistics, breast cancer imaging, Fourier methods, location error, magnetic resonance imaging methods, Markov random fields, medical imaging, image classification for differentiating dementia types, imaging of neurodegenerative diseases, spatial statistics, statistical consulting, statistical methods for medical imaging, statistical image reconstruction, voxel-based statistics.

CLINICAL ACTIVITIES

CLINICAL ACTIVITIES SUMMARY

PROFESSIONAL ACTIVITIES

MEMBERSHIPS

1998 - present	Royal Statistical Society
2000 - present	Institute of Mathematical Statistics
2002 - present	American Statistical Association
2003 - present	International Society for Bayesian Analysis
2020 - present	Computational and Methodological (CM) Statistics
2023 - present	Bernoulli Society

SERVICE TO PROFESSIONAL ORGANIZATIONS

2006 - 2006	Western North American Region of the International Biometric Society	Session Organizer for 2006 Annual Meeting
2006 - present	Center for Research and Technology, Thessaly, Greece	External Collaborator
2006 - 2007	Flinders University of South Australia	Statistical Consultant
2006 - 2007	The American Statistical Association, San Francisco Bay Area Chapter	Vice President of Biostatistics
2007 - 2008	The American Statistical Association, San Francisco Bay Area Chapter	President-Elect
2008 - 2009	The American Statistical Association, San Francisco Bay Area Chapter	President
2009 - 2009	International Chinese Statistical Association	Session Organizer for 2009 Annual Meeting
2010 - 2010	National Science Foundation (NSF)	Ad hoc reviewer
2010 - 2010	The American Statistical Association, San Francisco Bay Area Chapter	Past President
2010 - 2014	The American Statistical Association	Council of Chapters Representative for the San Francisco Bay Area Chapter

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2012 - 2012	National Institutes of Health (NIH) -- Neurological, Aging and Musculoskeletal Epidemiology Study Section (NAME)	Ad hoc reviewer
2014 - present	National Aeronautics and Space Administration (NASA)	Member of Finite Element Modeling (FE) Task Group
2015 - 2016	Complex Systems Model of Breast Cancer Etiology Project - funded by California Breast Cancer Research Program	Member of Advisory Committee
2015 - 2015	The American Statistical Association	Chair-Elect of the Statistics in Imaging Section
2016 - 2016	The American Statistical Association	Chair of the Statistics in Imaging Section
2016 - 2019	National Institutes of Health (NIH) -- Biostatistical Methods and Research Design Study Section (BMRD)	Ad hoc reviewer
2017 - 2017	National Institutes of Health (NIH) -- Special Section: NCI Clinical and Translational Exploratory/Developmental Studies (R21) and NCI Small Grants Program for Cancer Research (NCI Omnibus R03)	Ad hoc reviewer
2017 - 2017	Alzheimer's Association/GBHI -- Pilot Awards for Global Brain Health Leaders program	Ad hoc reviewer
2018 - 2021	Steering Committee Member for Annual Mettings of the Statistics in Imaging Section	Committee Member
2020 - 2020	National Institutes of Health (NIH) -- Special Emphasis Panel: Secondary Analyses of Existing Datasets in Heart, Lung, and Blood Diseases and Sleep Disorders (R21)	Ad hoc reviewer
2021 - 2021	Computational and Methodological Statistics (CMStatistics)	Scientific Program Committee Member
2021 - 2022	National Institutes of Health (NIH) -- Biostatistical Methods and Research Design Study Section (BMRD)	Study Section Member and Co-Chair
2022 - 2025	National Institutes of Health (NIH) -- Analytics and Statistics for Population Research Panel A Study Section (ASPA)	Study Section Member and Co-Chair
2022 - 2022	Computational and Methodological Statistics (CMStatistics)	Co-Chair
2023 - 2024	Workshop on Challenges in Neuroimaging Data Analysis	Organizing Committee Member

Appendix A

SERVICE TO PROFESSIONAL PUBLICATIONS

2004 - 2005	Scandinavian Journal of Statistics - ad hoc referee
2005 - 2006	Canadian Journal of Statistics - ad hoc referee
2005 - present	Biometrics - ad hoc referee
2007 - present	Magnetic Resonance in Medicine - ad hoc referee
2008 - present	Computer Methods and Programs in Biomedicine - ad hoc referee
2009 - 2013	Frontiers in Neuroscience - Review Editor
2009 - present	Journal of Neuroscience Methods - ad hoc referee
2009 - present	Annals of Neurology - ad hoc referee
2010 - present	Statistics in Medicine - ad hoc referee
2011 - present	Statistics and its Interface - ad hoc referee
2011 - present	Australian & New Zealand Journal of Statistics - ad hoc referee
2013 - present	IEEE Transactions on Medical Imaging - ad hoc referee
2017 - present	BMJ Open - ad hoc referee
2017 - present	Journal of the Royal Statistical Society, Series C, Applied Statistics - ad hoc referee
2022 - present	Neuropsychologia - ad hoc referee
2022 - present	NeuroImage - ad hoc referee
2023 - present	Transactions on Biomedical Engineering - ad hoc referee
2024 - present	Magnetic Resonance Imaging - ad hoc referee

INVITED PRESENTATIONS - INTERNATIONAL

1999	"A Bayesian multiplicative Markov random field model of fMRI haemodynamic response parameters", Highly Structured Stochastic Systems Workshop on Statistical Modelling of Spatial and Space-Time Processes, Luminy, France	Invited Speaker
1999	"A Bayesian multiplicative Markov random field model for fMRI haemodynamic response parameters", Department of Statistics Seminar Series, University of Nottingham, UK	Invited Speaker
2006	"New statistical methods in functional imaging", Western North American Region of the International Biometric Society Meeting Session discussant, Flagstaff, AZ	Invited Discussant
2009	"K-Bayes Reconstruction", Frontiers in Imaging of Neurodegenerative Diseases - Satellite Symposium to the Annual Meeting of the Organization for Human Brain Mapping, San Francisco, CA	Invited Speaker

2009	"Statistical reconstruction of low-signal-to-noise-ratio MRI modalities", International Chinese Statistical Association Applied Statistics Symposium, San Francisco, CA	Invited Speaker
2010	"Introductory Concepts for Voxel-Based Statistical Analysis", Advanced Statistical Concepts for Multimodal MRI Workshop, San Francisco, CA	Invited Speaker
2014	"Bayesian Image Analysis in Fourier Space", Joint Statistical Meetings, Boston, MA	Invited Speaker
2015	"Bayesian Image Analysis in Fourier Space", Probability and Statistics Seminar Series, University of Nottingham, UK	Invited Speaker
2016	"Bayesian Image Analysis in Fourier Space", International Society for Bayesian Analysis World Meeting, Sardinia, Italy	Invited Speaker
2016	"Classifying dementia based on volumetric MRI", Joint Statistical Meetings, Chicago, IL	Invited Speaker
2018	"Bayesian image analysis in Fourier space for MRI data", Joint Statistical Meetings, Vancouver, British Columbia, Canada	Invited Speaker
2018	"A new approach to Bayesian image analysis", Department of Statistics Seminar, Athens University of Economics and Business, Greece	Invited Speaker
2018	"A new approach to Bayesian image analysis", International Conference of the ERCIM WG on Computational and Methodological Statistics, University of Pisa, Italy	Invited Speaker
2019	"Bayesian image analysis in transformed spaces", Statistics Meeting Following the Organization for Human Brain Mapping (OHBM) Meeting: Recent Advances on Modeling and Inference for Brain Signals and Images. Sapienza University of Rome, Italy	Invited Speaker
2019	"On the Bayesian spatial analysis of brain activation in fMRI", Joint Statistical Meetings, Denver CO	Invited Speaker
2019	"A Somewhat Gentle and Incomplete Introduction to Bayesian Image Analysis in 1) Image and 2) Fourier Space", Modern Statistical Methods: from Data to Knowledge, Krakow, Poland	Invited Speaker
2019	"Bayesian image analysis in transformed spaces (mostly Fourier)", Jerzy Neyman Statistical Session. Jubilee Congress for the 100th Anniversary of the Polish Mathematical Society, Krakow, Poland	Invited Speaker

2019	"A new approach to Bayesian image analysis (in transformed spaces)", Statistics 5, Aegina, Greece	Invited Speaker
2019	"Bayesian image analysis in transformed spaces", CMStatistics, London, UK.	Invited Speaker
2020	"Bayesian image analysis in Fourier space using data-driven priors (DD-BIFS)", International Conference on Information Processing and Management of Uncertainty in Knowledge-Based Systems. Lisbon, Portugal	Invited Speaker
2020	"Bayesian image analysis in Transformed spaces (BITS) and the BIFS/WIMP Python packages", Mini-Symposium on Advanced statistical methods for the analysis of high-dimensional data. Annual conference of the International Society for Clinical Biostatistics Meeting. Krakow, Poland.	Invited Speaker
2020	"Bayesian image analysis in Transformed spaces (BITS) and the BIFS/WIMP Python packages", CMStatistics, London, UK.	Invited Speaker
2021	"Bayesian image analysis in Fourier space (BIFS) models and some relationships with Markov random fields", King Abdullah University of Science and Technology, Saudi Arabia	Invited Speaker
2021	"Common problems in (bio)-statistics and data science and how to avoid them", King Abdullah University of Science and Technology, Saudi Arabia	Invited Speaker
2021	"Bayesian image analysis in Fourier space models and some relationships with Markov random fields", CMStatistics, London, UK.	Invited Speaker
2022	"Nonlinear Z-score estimation for establishing cognitive norms", Joint Statistical Meetings, Washington DC	Invited Speaker
2023	"Modeling longitudinal trajectories of dementia brain changes", BIRS-CMO Workshop: Statistical Challenges for Complex Brain Signals and Images, Oaxaca, Mexico	Invited Speaker
2023	"Bayesian image analysis in Fourier space (BIFS) models", International Indian Statistical Association Conference, Golden, Colorado	Invited Speaker
2023	"Bayesian image analysis in Fourier space (BIFS) models", EcoSta 2023, Tokyo, Japan	Invited Speaker
2023	"Some experiences designing Biostatistics and Data Science courses for Clinical Researchers", Joint Statistical Meetings, Washington DC	Invited Speaker

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2023	"Practical modeling of longitudinal neuropsychological and neuroimaging brain change", Modern Statistical Methods II, Krakow, Poland	Invited Speaker
2023	"Modeling longitudinal trajectories of dementia brain changes", CMStatistics 2023, Berlin, Germany	Invited Speaker

INVITED PRESENTATIONS - NATIONAL

2001	"Improved resolution of spectroscopic images using Bayesian reconstruction", Department of Statistics, The Ohio State University	Invited Speaker
2003	"Issues relating to the statistical analysis of fMRI hemodynamic response parameters", School of Public Health, The Ohio State University	Invited Speaker
2003	"Issues in the statistical analysis of fMRI data", Mathematical Biosciences Institute Workshop on Statistical and Mathematical Modeling of fMRI Data, The Ohio State University	Invited Speaker
2005	"Bayesian reconstruction of low resolution MR imaging modalities using high resolution structural MRIs as prior information", Department of Biophysics Seminar Series, Medical College of Wisconsin	Invited Speaker
2008	"K-Bayes Reconstruction of Physiologic MRI" Annual Meeting of the Society for Imaging Informatics in Medicine 8th Annual Research and Development Symposium, Seattle, WA	Invited Speaker
2015	"Bayesian Image Analysis in Fourier Space", Statistical Methods in Imaging Workshop, University of Michigan, MI	Invited Speaker
2017	"Bayesian Image Analysis in Fourier Space", Mathematics, Statistics, and Computer Science Colloquium, Marquette University, Milwaukee, WI	Invited Speaker
2017	"Estimating and validating dementia class probabilities based on volumetric MRI", Collaborative Case Study, Statistical Methods in Imaging Workshop, University of Pittsburgh, PA	Invited Speaker
2018	"Statistical analysis of MRI of the Breast in the Presence of Background Parenchymal Enhancement", Collaborative Case Study, Statistical Methods in Imaging Workshop, University of Pennsylvania, PA	Invited Speaker
2018	"Bayesian image analysis in Fourier space for Medical Imaging", Statistical Methods in Imaging Workshop, University of Pennsylvania, PA	Invited Speaker

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2018	"A new approach to Bayesian image analysis", Western Meeting of the American Mathematical Society, San Francisco State University, CA	Invited Speaker
2018	"A new approach to Bayesian image analysis", Workshop on Data Analytical Methods, National Institute of Aging, Alzheimer's Disease Centers Program Meeting, Atlanta, GA	Invited Speaker
2018	"Nonlinear Normative Score Calculators for NACC UDS V3 Cognitive Tests", National Institute of Aging, Alzheimer's Disease Centers Program Meeting, Atlanta, GA	Invited Speaker
2019	"Using brain atrophy measures to predict dementia onset in familial frontotemporal lobar degeneration", Statistical Methods in Imaging Workshop, University of California, Irvine, CA	Invited Speaker
2021	"Bayesian image analysis in transformed spaces (BITS) and the BIFS/WIMP packages", Statistical Methods in Imaging Workshop, Emory University, Atlanta, GA	Invited Speaker
2021	"Bayesian image analysis in Fourier space (BIFS) models and some relationships with Markov random fields", Cornell University, New York.	Invited Speaker
2021	"Bayesian image analysis in Fourier space (BIFS) models and some relationships with Markov random fields", Columbia University, New York.	Invited Speaker
2023	"Bayesian modeling for longitudinal trajectories of dementia brain changes", Statistical Methods in Imaging Workshop, University of Minnesota, Minneapolis, Minnesota	Invited Speaker
2023	"Modeling longitudinal trajectories of neuropsychological and neuroimaging brain changes", University of Pittsburgh, Pennsylvania.	Invited Speaker
2023	"Modeling longitudinal trajectories of dementia brain changes", University of North Carolina, Chapel Hill, North Carolina	Invited Speaker
2024	"Bayesian image analysis in Fourier space (BIFS)", Statistics in Imaging Working Group, Statistics in Imaging Section of American Statistical Association (via Zoom)	Invited Speaker

INVITED PRESENTATIONS - REGIONAL AND OTHER INVITED PRESENTATIONS

2002	"Improving resolution for studying brain biochemistry with MRSI", Neyman Seminar Series, Department of Statistics, UC Berkeley	Invited Speaker

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2008	"Bayesian Decision Analysis for Choosing Between Diagnostic Procedures", Meeting of the San Francisco Bay Area Chapter of the American Statistical Association	Invited Speaker
2014	"Bayesian Image Analysis in Fourier Space, with Applications in Medical Imaging", University of California, Davis Graduate Group in Biostatistics Seminar Series	Invited Speaker
2015	"Bayesian Image Analysis in Fourier Space, with Applications in Medical Imaging", Stanford Research Institute	Invited Speaker
2015	"Bayesian Image Analysis in Fourier Space, with Applications in Medical Imaging", Meeting of the San Francisco Bay Area Chapter of the American Statistical Association	Invited Speaker
2015	"Bayesian Image Analysis in Fourier Space (with Applications in Medical Imaging)", Genentech, South San Francisco	Invited Speaker
2016	"Bayesian Image Analysis in Fourier Space (with Applications in Medical Imaging)", University of California, Berkeley, Statistics and Genomics Seminar	Invited Speaker
2017	"Bayesian Image Analysis in Fourier Space", University of California, Santa Cruz, Jack Baskin School of Engineering	Invited Speaker
2017	"Bayesian Image Analysis in Fourier Space", Lawrence Livermore National Laboratories.	Invited Speaker
2017	"Bayesian Image Analysis in Fourier Space", University of California, Berkeley. Biostatistics Seminar Series	Invited Speaker
2017	"A Collection of UCSF Imaging and Spatial Datasets", University of California, Santa Cruz, Jack Baskin School of Engineering	Invited Speaker
2017	"Non-linear Z-scores calculation for Neuropsych data" ARTFL/LEFFTDS Investigators Meeting, New Orleans, LA	Invited Speaker
2018	"Validation and the automated classification of dementias with MRI", Lawrence Livermore National Laboratories.	Invited Speaker
	UCSF PRESENTATIONS:	
2000	"A Bayesian multiplicative MRF model of fMRI hemodynamic response parameters", MR Unit, VAMC/UCSF	Invited Speaker
2003	"Issues in the statistical analysis of fMRI data", Department of Epidemiology and Biostatistics, UCSF	Invited Speaker

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2004	"Improving the effective resolution of low signal magnetic resonance imaging modalities by incorporating high resolution structural information", Department of Epidemiology and Biostatistics, UCSF	Invited Speaker
2004	"A Bayesian spatial analysis of fMRI data along with some issues for modeling the hemodynamic response", Cogneuro Meeting, Department of Radiology, UCSF	Invited Speaker
2004	"Issues in the statistical analysis of fMRI data", Neuroradiology Conference, Department of Radiology, UCSF	Invited Speaker
2004	"Statistics for medical imaging", Neuroradiology Conference, Department of Radiology, UCSF	Invited Speaker
2005	"Improved resolution for low resolution magnetic resonance imaging modalities", MR Unit, Brain Imaging Research Seminar Series, Department of Radiology, UCSF	Invited Speaker
2005	"Introduction to Markov chain Monte Carlo methods for Bayesian image analysis", MR Unit, Workgroup on Acquisition Reconstruction and Processing Seminar Series, Department of Radiology, UCSF	Invited Speaker
2005	"Introduction to Classification Methods", Center for Imaging of Neurodegenerative Diseases, Brain Imaging Research Seminar Series, UCSF	Invited Speaker
2006	"An Overview of Survival Analysis", Center for Imaging of Neurodegenerative Diseases, Brain Imaging Research Seminar Series, UCSF	Invited Speaker
2006	"Introduction to Bayesian Statistics", Center for Imaging of Neurodegenerative Diseases, Brain Imaging Research Seminar Series, UCSF	Invited Speaker
2006	"Bayesian Decision Analysis for Choosing Between Diagnostic Methods", Department of Epidemiology and Biostatistics Program Meeting, UCSF	Invited Speaker
2007	"Regression Towards the Mean and the Prediction of Cognitive Decline", Center for Imaging of Neurodegenerative Diseases, Department of Radiology and Biomedical Imaging, UCSF	Invited Speaker
2007	"Bayesian Methods for PET/CT and SPECT/CT" - Center for Molecular and Functional Imaging, Department of Radiology and Biomedical Imaging, UCSF	Invited Speaker
2009	"Are correlations in social neuroscience really Voodoo?" Neuroscience Imaging Center fMRI Research Meeting, UCSF	Invited Speaker

2015	"Bayesian Image Analysis in Fourier Space, with Applications in Medical Imaging", Center for Imaging of Neurodegenerative Diseases, Department of Radiology and Biomedical Imaging, UCSF	Invited Speaker
2015	"An Overview of Bayesian Statistics, with Applications in Medical Imaging", Department of Neurology, Memory and Aging Center Grand Rounds	Invited Speaker
2015	"Bayesian Statistics 2: Bayesian Image Analysis, and Bayesian Image Analysis in Fourier Space", Department of Neurology, Memory and Aging Center Grand Rounds	Invited Speaker
2018	"Bayesian Image Analysis in Fourier Space and Potential Application for Breast MRI", Breast Research Interest Group Meeting, Department of Radiology and Biomedical Imaging	Invited Speaker
2021	"Computational Methods in Digital Health", Department of Epidemiology and Biostatistics Digital Health Initiative.	Invited Speaker and Panelist
2022	"Nonlinear normative scores for cognitive testing", UCSF Weill Institute for Neurosciences/Memory and Aging Center.	Invited Speaker
2022	"Bayesian statistics, Bayesian Image Analysis, and extensions to Fourier space (with an application in FTD diagnosis). UCSF Weill Institute for Neurosciences/Memory and Aging Center.	Invited Speaker
2022	"Two very different examples of statistical methodology development for understanding dementia." UCSF Weill Institute for Neurosciences/Memory and Aging Center.	Invited Speaker

GOVERNMENT AND OTHER PROFESSIONAL SERVICE

2007 - 2007	Advanced MRI Technologies, Sebastapol CA	Statistical consultant
2007 - 2008	Orthokinematics, San Francisco, CA	Statistical consultant
2011 - 2016	Bioclinica and Synarc, Newark, CA	Statistical consultant
2015 - 2015	Goodman Neuman Hamilton LLP	Expert witness / statistical consultant
2015 - 2015	Kelley Drye and Warren LLP	Expert witness / statistical consultant

2015 - 2016	Carlson, Caspers, Vandenburgh, Lindquist & Schuman	Expert witness / statistical consultant
2016 - present	Winston & Strawn LLP	Expert witness / statistical consultant
2016 - 2017	Haynes and Boone, LLP	Expert witness / statistical consultant
2017 - present	Latham and Watkins, LLP	Expert witness / statistical consultant
2020 - 2020	REsurety, Inc	Statistical consultant
2020 - 2021	Price, Parkinson, and Kerr, PLLC	Expert witness / statistical consultant
2022 - 2023	Cornerstone Research	Expert witness / statistical consultant

UNIVERSITY AND PUBLIC SERVICE

SERVICE ACTIVITIES SUMMARY

My service activities service activities have been focused on my work as 1) the head of the UCSF Department of Epidemiology and Biostatistics Data Science Program; 2) Director of the CTSI Biostatistical Consulting Unit; 3) Departmental committee work, and 4) Reviewing for the NIH Analytics and Statistics for Population Research Panel A (ASPA) Study Section Study Section as a standing member.

1) In my role as Head of the Data Science Program I am responsible for developing the Data Science for Medicine education program at UCSF. This has culminated in the successful roll-out of the new Masters of Science and Certificate programs in Health Data Science (MiHDaS/CiHDaS) now in its second year. 2) I am Director of the Biostatistics Consulting Unit (BCU) with the UCSF Clinical and Translational Sciences Institute (CTSI). My work in this capacity involves managing a group of 4 salaried faculty consultants and 2 analysts as well as 15 hourly paid faculty consultants. The BCU provides campus-wide statistical consultation and collaboration, including help with optimal experimental designs, data analysis, reporting of results, and drafting or editing grant and paper statistical sections. 3) I am involved in numerous departmental committees including being a member of the Educational Leadership Group (ELG), Curriculum Evaluation Committee, Training in Clinical Research MAS program advisory committee, and the UCB-UCSF Computational Precision Health Sciences PhD program Executive Committee. 4) I have served as a standing member on the NIH Biostatistical Methods and Research Design (BMRD) and Analytics and Statistics for Population Research Panel A (ASPA) Study Sections.

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UNIVERSITY SERVICE
UC SYSTEM AND MULTI-CAMPUS SERVICE

2018 - present	University of California, Santa Cruz, Graduate Division, Applied Mathematics and Statistics	Qualifying Exam Committee Member for Wenjie Zhao
2018 - present	University of California, Santa Cruz, Graduate Division, Applied Mathematics and Statistics	Qualifying Exam Committee Member for Laura Baracaldo
2018 - present	Data Safety and Monitoring Board for RCT of Phase II RCT of High-dose Vitamin D Supplements in Older Adults. PI John Olichney, UC Davis	Board Member and Current Chair
2020 - 2021	University of California, Berkeley -- University of California, San Francisco, Joint Program Working Group for PhD program in Computational Precision Medicine	Member
2021 - present	Data Safety and Monitoring Board for RCT evaluating in-home assistive technology for dementia caregivers, University of California, Berkeley, and People Power	Board Member and Chair
2021 - present	Computational Precision Health Graduate Group: University of California, Berkeley -- University of California, San Francisco	Executive Committee Member

UCSF CAMPUSWIDE

2006 - 2010	University of California, San Francisco, Department of Radiology and Biomedical Imaging	Director of the Biostatistics Consulting Service
2009 - present	Clinical and Translational Sciences Institute	Biostatistics Consultant
2010 - 2010	Robert Wood Johnson Foundation Health and Society Scholars program	Interviewer
2011 - present	Research Allocation Program Digital Health Research Committee (previously Mobile Health Research Committee)	Committee Member/ Reviewer
2014 - present	Clinical and Translational Sciences Institute	Director of Biostatistics Consulting Unit
2016 - 2016	Data Safety and Monitoring Board for Radiation Dose Study at UCSF. PI Rebecca Smith-Bindman	Board Member

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DEPARTMENTAL SERVICE

-	DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS:	
2014 - 2014	Big Data Subcommittee	Subcommittee Member
2015 - 2017	Divisions of Biostatistics and Bioinformatics	Seminar Series Organizer
2015 - 2016	Reviewing Epidemiology PhD applications	Reviewer
2015 - 2016	Succession Committee	Committee Member
2017 - 2019	Search Committee for Biostatistics faculty positions	Committee Member
2017 - present	Data Science Subcommittee	Committee Member
2018 - 2019	Strategic Partnerships Working Group	Chair
2018 - 2019	Working group to examine Department of Epidemiology and Biostatistics organizational structure	Working group Member
2018 - present	Training in Clinical Research Advisory Committee	Member
2019 - present	Educational Leadership Group	Member
2020 - present	Curriculum Evaluation Committee	Member
2021 - 2021	Search Committee for new Head of Training in Clinical Research MAS and Certificate programs	Member
-	DEPARTMENT OF RADIOLOGY AND BIOMEDICAL IMAGING:	
2005 - 2005	Search Committee for an Assistant/Associate Professor position	Committee Member
2006 - 2007	Center for Molecular and Functional Imaging Committee for Fundraising	Committee Member
2007 - present	Department of Radiology and Biomedical Imaging Seed Grant Committee	Committee Member
2010 - 2010	Search Committee for an Assistant Professor position	Committee Member

SERVICE AT OTHER UNIVERSITIES

1997 - 1998	Postgraduate Representative Research Committee for the Department of Mathematics	University of Nottingham, UK

1997 - 2004	Webmaster and Mailing List Organizer	International Highly Structured Stochastic Systems (HSSS) organization
1998 - 1999	School of Mathematical Sciences Postgraduate Representative	Faculty of Science, University of Nottingham, UK

TEACHING AND MENTORING

TEACHING SUMMARY

As Head of the Data Science Program in the Department of Epidemiology and Biostatistics I have led the work to develop and run the new and successful Self-Supporting Master's of Science and Certificate's programs in Health Data Sciences. The program is now in its second year. For the first year we had 6 students who have now progressed to the Capstone projects of their second year. In the second year of running the program we have 22 new students.

In 2023/2024, I have been directing the Seminar programs for both the first year (Datasci 220) and second year (Datasci 221) health data science programs. In the first year, the seminars largely focus on UCSF and outside speakers presenting their research and proposing potential projects the students might be interested in getting involved with for Capstones. Also covered in these seminars are isolated topics in data science such as sample size calculations and ethical considerations. In the second year seminars, there is a transition toward students presenting the progress on their Capstone projects and receiving feedback from their fellow students and faculty. In both years students also have the opportunity to raise topics of their own and discuss general concerns.

In 2019 I developed a new course that was taught for the first time in the Spring of 2019 called Machine Learning with R for the Biomedical Sciences. I have now passed that course to a new faculty member and am now developing new courses on 1) Bayesian Statistics and Gaussian processe; and 2) Statistical and Data Science methods for medical imaging. These courses are hoped to begin 2024/2025.

Prior to 2018, my primary teaching activity was focussed on my role as Course Director of BIOSTAT 202 and BIOSTAT 209. BIOSTAT 202 is a course that I developed with my colleagues Drs. Charles McCulloch and Elaine Allen. The course was given for the first time in Summer 2016 and provides an introduction to the analysis of "Big Data" in biomedicine. BIOSTAT 209 is a biostatistics component of the UCSF TICR program focused on advanced statistical regression methods. I directed BIOSTAT 209 for the first time in Spring 2011 and ran the course annually until Spring of 2017. As Course Director for both courses, I organized the course structure, provide four 90 minute lectures each, organize the project component of the courses, and led homework sessions, labs and project sessions for each course.

Before taking over BIOSTAT 209 I had developed a new UCSF course: Radiology 170.06, Statistics for Radiology and Biomedical Imaging. The course consisted of ten two-hour lectures and was presented for the first time in Spring 2009 at UCSF. The course introduced statistical methods particularly relevant to people involved in the radiological/imaging sciences, where specialized statistical techniques or approaches are often required. Because this was primarily

a non-statistical audience with a wide research background, this course required a delicate balance between providing enough information to explain the key statistical concepts while avoiding too much technical detail.

Additionally, I have lectured for the UCSF Department of Radiology lecture courses "Imaging Study Design" and "Medical Imaging Informatics".

I have mentored (and continue to mentor) numerous NIH K-grant awardees in the fields of biostatistics, data science, epidemiologic applications as well as clinical studies.I also act as a Committee Advisor for TICR program Masters students and I continue to provide informal lectures and teach students, postdoctoral researchers, residents, fellows and faculty on a one-to-one basis. This one-to-one teaching/mentoring activity primarily consists of work performed as a CTSI Biostatistics consultant, as well as work mentoring Training in Clinical Research (TICR) Masters students.

FORMAL TEACHING

	Academic Yr	Course No. & Title	Teaching Contribution	School	Class Size
	2001 - 2002	Biophysics 203: Foundations for Mathematical Biology	Guest Lecturer: one 90 minute lecture	Grad	25-30
	2004 - 2005	Radiology 197: Statistics for Radiology Research.	Lecturer: five 90 minute lectures		20-25
	2005 - 2006	Radiology 170.03: Medical Imaging Informatics	Lecturer: one 120 minute lecture		5
	2006 - 2007	Radiology 170.03: Medical Imaging Informatics	Lecturer: one 120 minute lecture		6
	2006 - 2006	Lecture series: "Statistics for Radiology Residents". This course was directly pitched to Residents within the Department of Radiology and therefore aimed to provide enough information to explain the key statistical concepts while retaining minimal technical detail.	Joint Director with Dr. Ying Lu. I lectured on Repeated and Correlated Measures, Longitudinal Data Analysis, Time Series Models, Mixed Effects Models and Survival Analysis.		

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	Academic Yr	Course No. & Title	Teaching Contribution	School	Class Size
	2007 - 2008	Radiology 170.03: Medical Imaging Informatics	Lecturer: one 120 minute lecture		5
	2008 - 2009	Radiology 170.03: Medical Imaging Informatics	Lecturer: one 120 minute lecture		10
	2008 - 2009	Radiology 170.06: Statistics for Radiology and Biomedical Imaging	Course Director and Lecturer: I teach 5 of 10 120 minute lectures		15-25
	2009 - 2010	IDS 102A: Organ Systems: Topics in Cardiovascular Pathophysiology, Epidemiology, Pharmacology & Physiology	Small Group Leader - 2 sessions	Medicine	12
	2009 - 2010	IDS 106: Mechanisms, Methods and Malignancy (M3) - Small Group Evidence Based Medicine	Small Group Leader - 2 sessions	Medicine	12
	2009 - 2010	Radiology 170.03: Medical Imaging Informatics	Lecturer: one 120 minute lecture		10
	2010 - 2011	IDS 106: Mechanisms, Methods and Malignancy (M3) - Small Group Evidence Based Medicine	Small Group Leader - 2 sessions	Medicine	13
	2010 - 2011	Radiology 170.03: Medical Imaging Informatics	Lecturer: one 120 minute lecture		10

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	Academic Yr	Course No. & Title	Teaching Contribution	School	Class Size
	2010 - 2011	BIOSTAT 209: Biostatistical Methods for Clinical Research III	Course Director and Lecturer	Grad	58
	2011 - 2012	IDS 106: Mechanisms, Methods and Malignancy (M3) - Small Group Evidence Based Medicine	Small Group Leader - 2 sessions		13
	2011 - 2012	Radiology 170.03: Medical Imaging Informatics	Lecturer: one 120 minute lecture		5
	2011 - 2012	Radiology 205: Imaging Study Design	Guest Lecturer: one 120 minute lecture	Grad	10
	2011 - 2012	BIOSTAT 209: Biostatistical Methods for Clinical Research III	Course Director and Lecturer	Grad	62
	2012 - 2013	Radiology 170.03: Medical Imaging Informatics	Lecturer: one 120 minute lecture		8
	2012 - 2013	Radiology 205: Imaging Study Design	Guest Lecturer: two 90 minute consulting lectures	Grad	16
	2012 - 2013	BIOSTAT 209: Biostatistical Methods for Clinical Research III	Course Director and Lecturer		49
	2012 - 2013	EPI 150.03: Designing Clinical Research (One Month)	Guest Lecturer: one 75 minute lecture		70
	2013 - 2014	Radiology 170.03: Medical Imaging Informatics	Lecturer: one 120 minute lecture		10

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	Academic Yr	Course No. & Title	Teaching Contribution	School	Class Size
	2013 - 2014	Biostat 209: Biostatistical Methods for Clinical Research III	Course Director and Lecturer	Grad	63
	2013 - 2014	Radiology 205: Imaging Study Design	Guest Lecturer: two 90 minute consulting lectures	Grad	16
	2013 - 2013	Short course: Two day course on "Survival Analysis" at the UCSF Bixby Center.	I created and gave all of the short course. The course included 50% lectures and 50% labs.		
	2014 - 2015	Radiology 170.03: Medical Imaging Informatics	Lecturer: one 120 minute lecture		6
	2014 - 2015	Biostat 209: Biostatistical Methods for Clinical Research III	Course Director and Lecturer	Grad	51
	2014 - 2015	Radiology 205: Imaging Study Design	Guest Lecturer: two 90 minute consulting lectures	Grad	16
	2015 - 2016	Biostat 209: Biostatistical Methods for Clinical Research III	Course Director and Lecturer	Grad	71
	2015 - 2016	Radiology 205: Imaging Study Design	Guest Lecturer: two 90 minute lectures	Grad	16
	2016 - 2017	Biostat 202: Opportunities and Challenges of Complex Biomedical Data: Introduction to the Science of "Big Data"	Course Director and Lecturer	Grad	50
	2016 - 2017	Biostat 209: Biostatistical Methods for Clinical Research III	Course Director and Lecturer	Grad	43
	2016 - 2017	Radiology 205: Imaging Study Design	Guest Lecturer: two 90 minute lectures	Grad	16

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	Academic Yr	Course No. & Title	Teaching Contribution	School	Class Size
	2017 - 2018	Biostat 202: Opportunities and Challenges of Complex Biomedical Data: Introduction to the Science of "Big Data"	Course Director and Lecturer	Grad	34
	2018 - 2019	Biostat 216: Machine Learning in R for the Biomedical Sciences	Course Director and Lecturer	Grad	17
	2019 - 2020	Biostat 216: Machine Learning in R for the Biomedical Sciences	Course Director and Lecturer	Grad	15
	2020 - 2021	Bioengineering 245: Machine Learning Algorithms for Medical Imaging	Guest Lecturer	Grad	10
	2022 - 2023	Bioengineering 245: Machine Learning Algorithms for Medical Imaging	Guest Lecturer	Grad	10
	2023 - 2024	Datasci 220: Data Science Program Seminar I	Course Director	Grad	26
	2023 - 2024	Datasci 221: Data Science Program Seminar II	Course Director	Grad	8
	-	FORMAL SCHEDULED CLASSES AT OTHER INSTITUTIONS:			

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	Academic Yr	Course No. & Title	Teaching Contribution	School	Class Size
	1999 - 2000	H71QMT: Quantitative Methods, School of Mechanical, Materials, Manufacturing Engineering and Management, University of Nottingham, UK	Lecturer of 22 one hour lectures plus 11 one hour tutorials		50-55
	2002 - 2003	Statistics 428: Introduction to Probability and Statistics for Engineering and the Sciences II, Department of Statistics, The Ohio State University	Lecturer of 30 one hour lectures plus 30 office hours/problems classes		45-50

INFORMAL TEACHING

2003 - present Informal adviser and consultant for numerous students, postdoctoral researchers, residents, fellows and faculty at UCSF concerning clinical studies, applied statistical problems, and development of new statistical methods. In addition, biostatistical consulting through CTSI involves a large informal educational component.

2006 - 2006 Lecture series: "Statistics for Radiology Residents". This course was directly pitched to Residents within the Department of Radiology and therefore aimed to provide enough information to explain the key statistical concepts while retaining minimal technical detail. I was Joint Director with Dr. Ying Lu. I lectured on Repeated and Correlated Measures, Longitudinal Data Analysis, Time Series Models, Mixed Effects Models and Survival Analysis.

2013 - 2013 Short course: Two day course on "Survival Analysis" at the UCSF Bixby Center. I created and gave all of the short course. The course included 50% lectures and 50% labs.

2021 - 2021 Short course, 1 week: "Machine learning in R with applications in the biomedical sciences" at the Athens University of Economics and Business.

MENTORING SUMMARY

I am an advisor for a PhD students in the Epidemiology program (Vignesh Arasu and Chloe Eng). I am also a mentor to Drs. Adam Staffaroni, Spina Salvatore, and Thu Nguyen for their respective NIH K-awards.
In addition, I am currently acting as a Master's students for the UCSF Training in Clinical Research (TICR) program and am a mentor to four recent early career recruitments that have

focus in machine learning methods and the analysis of medical imaging. Finally, my consulting work through CTSI and elsewhere requires me to regularly mentor residents, fellows and students across campus.

PREDOCTORAL STUDENTS SUPERVISED OR MENTORED

Dates	Name	Program or School	Mentor Type	Role	Current Position
2006 - 2006	Johanna Zumer	Bioengineering	Research/Scholarly Mentor	PhD committee member	PhD Student
2007 - 2010	Hao Zhang	Department of Biostatistics, University of California, Davis	Research/Scholarly Mentor	Joint Advisor	PhD Student
2007 - 2007	Qian Zhao	Visiting student to Department of Radiology from Sen Yat-San University, Guangxhou, China	Research/Scholarly Mentor	Joint Advisor	PhD Student
2012 - 2012	Alex Pankov	Epidemiology PhD Program, UCSF. BIO MI INF 221 Informatics rotation	Research/Scholarly Mentor	Spring Rotation Advisor	PhD Student
2013 - 2014	Patti Curl	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Master's Committee Advisor	Training in Clinical Research Master's Student

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Dates	Name	Program or School	Mentor Type	Role	Current Position
2014 - 2015	Susan Lee	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Master's Committee Advisor	Training in Clinical Research Master's Student
2014 - 2015	Jessica Cruz-Whitely	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Master's Committee Advisor	Training in Clinical Research Master's Student
2015 - 2016	Bardia Nourbakhsh	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Master's Committee Advisor	Training in Clinical Research Master's Student
2016 - 2017	Vignesh Arasu	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Master's Committee Advisor	MD Training in Clinical Research Master's Student
2016 - 2017	Anoop Sheshadri	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Master's Committee Advisor	MD Training in Clinical Research Master's Student

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Dates	Name	Program or School	Mentor Type	Role	Current Position
2017 - 2017	Douglas Myers-Turnbull	Bio-Medical Informatics Graduate Program	Research/Scholarly Mentor	Qualifying committee member and advisor	PhD Student
2017 - 2021	Vignesh Arasu	Epidemiology PhD Program, UCSF	Research/Scholarly Mentor,Project Mentor	Advisor	PhD Student
2018 - 2019	Monica Ospina-Romero	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Master's Committee Advisor	Training in Clinical Research Master's Student
2018 - 2021	Chloe Eng	Epidemiology PhD Program, UCSF	Research/Scholarly Mentor	Chair of Qualifying Exam Committee and F31 mentor	PhD Student
2020 - 2021	Carol Tran	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Qualifying committee member and advisor	Training in Clinical Research Master's Student
2020 - 2021	Sophia Hernandez	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Qualifying committee member and advisor	Training in Clinical Research Master's Student
2021 - 2021	Kostandinos Bakas	Athens University of Economics and Business	Research/Scholarly Mentor	Advisor for undergraduate thesis	Undergraduate Student

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Dates	Name	Program or School	Mentor Type	Role	Current Position
2021 - 2022	Carmen Lee	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Qualifying committee member and advisor	Training in Clinical Research Master's Student
2021 - 2022	Hannah Hoban	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Qualifying committee member and advisor	Training in Clinical Research Master's Student
2021 - 2022	Matthew Durstenfeld	Epidemiology and Biostatistics/ CTSI: Training in Clinical Research Program	Research/Scholarly Mentor	Qualifying committee member and advisor	Training in Clinical Research Master's Student
2018 - 2022	Laura Baracaldo	University of California, Santa Cruz	Research/Scholarly Mentor	Qualifying and dissertation committee member	PhD Student
2021 - present	Jingxuan Wang	Epidemiology PhD Program, UCSF	Research/Scholarly Mentor,Project Mentor	Qualifying and dissertation committee member and F99/K00 award mentor	PhD Student

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POSTDOCTORAL FELLOWS AND RESIDENTS MENTORED

Dates	Name	Fellow	Mentor Role	Faculty Role	Current Position
2003 - 2005	Satoru Hayasaka, PhD	Radiology, Postdoc	Research/Scholarly Mentor,Project Mentor,Career Mentor	Joint Advisor	Asst. Prof. of Biostatistical Sciences and Radiology, Wake Forest University School of Medicine
2003 - 2005	Enmin Song, PhD	NCIRE, Scientific Programming Specialist	Research/Scholarly Mentor,Project Mentor,Career Mentor	Joint Advisor	Professor, Huazhong University of Science and Technolgy, Wuhan, China
2010 - 2010	Sharon Kwan, MD	Radiology Resident	Research/Scholarly Mentor	Mentor for Department of Radiology and Biomedical Imaging Seed Grant application	UCSF Radiology and Biomedical Imaging Resident
2017 - 2017	Yingjia Chen	Postdoctoral Fellow	Research/Scholarly Mentor,Project Mentor,Career Mentor	Joint Advisor	Senior Data Analyst, Genentech.
2017 - 2018	Teresa Filshtein	Postdoctoral Fellow	Research/Scholarly Mentor,Career Mentor	Co-Advisor	Postdoctoral Fellow, UCSF Department of Epidemiology and Biostatistics
2018 - present	Thu Nguyen	Associate Specialist	Research/Scholarly Mentor,Project Mentor	K99 Mentor	Associate Specialist, UCSF Departement of Epidemiology and Biostatistics

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FACULTY MENTORING

Dates	Name	Position while Mentored	Mentor Type	Mentoring Role	Current Position
2008 - 2010	Timothy Durazzo, PhD	Assistant Adjunct Professor of Radiology and Biomedical Imaging	Research/Scholarly Mentor	K-award mentor	Assistant Adjunct Professor of Radiology and Biomedical Imaging
2014 - 2019	Howard J. Rosen	Professor of Neurology	Research/Scholarly Mentor	K-award mentor	Professor of Neurology
2016 - 2021	Spina Salvatore, MD	Assistant Adjunct Professor of Neurology	Research/Scholarly Mentor	K-award mentor	Assistant Adjunct Professor of Neurology
2019 - 2024	Adam Staffaroni, PhD	Assistant Professor, UCSF Memory & Aging Center	Research/Scholarly Mentor	K-award mentor	Assistant Professor of Neurology
2020 - present	Aaron Scheffler, PhD	Assistant Professor of Epidemiology and Biostatistics	Research/Scholarly Mentor	Primary faculty mentor	Assistant Professor of Epidemiology and Biostatistics
2020 - present	Efstathios Gennatas, PhD	Assistant Professor of Epidemiology and Biostatistics	Research/Scholarly Mentor,Career Mentor	Primary faculty mentor	Assistant Professor of Epidemiology and Biostatistics
2020 - present	Jean Feng, PhD	Assistant Professor of Epidemiology and Biostatistics	Research/Scholarly Mentor,Career Mentor	Teaching mentor	Assistant Professor of Epidemiology and Biostatistics
2020 - present	Fei Jiang, PhD	Assistant Professor of Epidemiology and Biostatistics	Research/Scholarly Mentor,Project Mentor,Career Mentor	Primary faculty mentor	Assistant Professor of Epidemiology and Biostatistics

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Dates	Name	Position while Mentored	Mentor Type	Mentoring Role	Current Position
2021 - present	Lawren VandeVrede MD/PhD	Assistant Professor of Neurology	Research/Scholarly Mentor,Project Mentor	K-award mentor	Assistant Professor of Neurology
2023 - present	Matthew Durstenfeld MD	Assistant Professor of Medicine		K-award mentor	Assistant Professor of Medicine

RESEARCH AND CREATIVE ACTIVITIES

RESEARCH AND CREATIVE ACTIVITIES SUMMARY

My research activities are geared toward the development and application of statistical methods for research in medical imaging with applications in dementia and breast cancer. My overall goal is to develop methods that can improve and expand medical imaging and its impact in areas such as clinical diagnosis and prognosis, clinical trial biomarker development and disease severity assessment. From a medical imaging perspective, my latest primary research direction is in the development of new Bayesian image analysis statistical methodology that is formulated in Fourier space -- i.e. in terms of spatial frequencies which has the potential to revolutionize the field in terms of computational speed and simplicity as well as providing for an expanded set of problems that can be solved. I also have other ongoing research areas in image reconstruction and analysis of a range of non-invasive magnetic resonance imaging (MRI) modalities focused on imaging the human brain. From a statistical perspective, my primary research focus is on spatial, time-series and space-time modeling. In particular, I have published in the three major fields of spatial statistics: lattice/image analysis, spatial point processes, and continuous spatial process. In addition, I am involved in numerous large scale collaborative problems in the fields of medical imaging and these compose the majority of my research time as can be seen in my publication list.

Bayesian image analysis in Fourier space: The objective of this project is to develop a family of new medical imaging processing methods that will provide improvements over current practices. The approach is to reformulate Bayesian Image analysis into Fourier Space (BIFS). The originally inter-correlated and high-dimensional problem in image space is broken down into a set of independent one-dimensional problems in Fourier space (tied together by the new concept of a parameter function). The Fourier space independence enables development of powerful and easy to specify BIFS models with fast algorithms to compute posterior image estimates. BIFS will be applied to problems in breast cancer detection and delineating patterns of brain blood perfusion associated with dementia. An open-source software library has been developed for dissemination to the scientific community.

Magnetic resonance imaging (MRI) modality reconstruction: Innovative MRI modalities of the human brain promise to reveal biological changes that accompany neurodegenerative disease, psychiatric illness and brain injury. These modalities are capable of imaging blood perfusion (perfusion MRI), metabolite concentrations (magnetic resonance spectroscopic imaging, MRSI), and neural activation (functional MRI or fMRI). However, perfusion MRI, fMRI and MRSI have had limited clinical impact because they inherently rely on biophysical signals that are exceedingly subtle. Therefore, these MRI modalities must be imaged with poorer signal-to-noise-ratio (SNR) and at lower spatial resolution than conventional structural MRI. The objective of my MRI reconstruction work is to improve image quality and resolution by

fusing low-SNR raw imaging data with high-resolution/high-SNR anatomical information, e.g., from structural MRI. The method of fusing is through a Bayes rule with the anatomical information incorporated via a prior distribution. The fusion of raw data and anatomical information in this principled fashion leads to greatly improved image reconstruction of the low-SNR modality. These improvements can be seen visually and numerically in terms of accuracy, precision, artifact reduction and resolution. The improved image accuracy and precision of these new reconstruction techniques provides for more powerful determination of disease specific effects across subjects. This increased power enables the potential use of these methods for determining biomarkers in clinical studies and improving diagnostic prediction for a range of neurodegenerative diseases, psychiatric conditions and brain injuries. My reconstruction methodology can be readily generalized to non-brain and non-MRI based imaging, leading to exciting potential applications in cardiac imaging, positron emission tomography, single photon emission tomography, ultrasound and MEG/EEG etc.

Functional magnetic resonance imaging (FMRI) analysis: FMRI signal detection is primarily focused on detecting signal changes in response to stimuli, actions or thoughts - the hemodynamic response signal (HDR). Interest lies in detecting and spatially defining patterns of change between different experimental conditions or how these patterns differ between one set of subjects and another (e.g. patients versus controls). My work on post-reconstruction statistical analysis is focused on improving detection and delineation of activation response patterns observed with functional MRI (fMRI). These improvements are based on improved time series and spatial statistical modeling designed to capture characteristics of brain responses that are missed by standard methods. I have developed new statistical models of the HDR that relax the overly restrictive parametric assumptions of standard methods. These new models are able to capture variation in the shape of the HDR across spatial locations that has not been seen before. The detection and description of this spatial variation has direct biological and clinical relevance. Furthermore, quantification of this spatial variation in HDR can increase statistical power to detect differences in HDR signals under different experimental conditions and between different disease groups. This increase in power has positive implications for generating clinical biomarkers of neurodegenerative disease, psychiatric illness and brain injury as well as improving diagnostic accuracy and optimal treatment strategy.

Decision analysis for diagnostic testing: I am developing a new Bayesian decision analysis approach for choosing between competing diagnostic technologies. Medical institutions often need to make decisions as to whether to introduce a new diagnostic procedure or to continue with an existing one and this decision can be particularly important in the field of medical imaging where costs are typically very high. My quantitative (Bayesian utility) approach to solving this decision problem provides an optimal balance between diagnostic accuracy and cost for deciding a) whether or not to introduce a new diagnostic procedure, or b) which of many procedures to assign individuals to. My approach accounts for costs of diagnosis and treatment, as well as consideration of quality of life improvements gained by more accurate diagnosis**.**

Collaborative/translational research: Outside of my individual research I perform extensive collaborative research activities with a particular focus on medical imaging/radiological research. This research forms the bulk of my work at UCSF. Many of these projects utilize my statistical expertise in longitudinal modeling, spatial and time series techniques. Many of these projects these projects are in the field of brain imaging for the study of illnesses such as multiple sclerosis, Alzheimer's disease, fronto-temporal lobe dementia, Gulf War illness, amyotrophic lateral sclerosis, human immunodeficiency virus, post-traumatic stress disorder, Creutzfeldt-Jakob disease, and corticobasal syndrome. I also work on many imaging problems outside the brain such as the study of breast cancer, thyroid cancer, prostate cancer, and osteoporosis/space-flight bone loss.

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RESEARCH AWARDS - CURRENT

1. 1U19AG063911-01 | Co-Investigator | 20 % effort | Boeve (PI)
NIH | 09/15/2019 | 06/30/2024
ARTFL LEFFTDS Longitudinal Frontotemporal Lobar Degeneration (ALLFTD)
This project will expand a North American research network that is preparing for clinical trials for FTLD.
Statistician

2. 2P01CA210961-06A1 | Co-Investigator | 20 % effort | Esserman (PI)
NIH/NCI | 07/01/2023 | 06/30/2028
The I SPY 2.2 TRIAL: Evolving to Imaging and Molecular Biomarker Response Directed Adaptive Sequential Treatment to Optimize Breast Cancer Outcomes
We have designed a clinical trial for women treated with drugs for early breast cancer before surgery, in which patients whose cancers do not respond to the initial experimental treatment can be switched to receive a different proven therapy that is considered the best for their particular type of cancer. Our goal is to develop a system that continuously improves our ability to provide each woman with the best chance at being cured, while also trying to avoid any unnecessary treatments that cause toxic side effects.
Statistician

3. R01 AG062758 | Co-Investigator | 10 % effort | Perry (PI)
NIH/NIA | 08/15/2020 | 04/30/2025
Diagnostic and prognostic certainty in behavioral variant frontotemporal dementia | $ 4,018,729 total
The overarching goal of the proposed study is to improve diagnostic and predictive accuracy in bvFTD from the time of the first visit. Clinicians need guidance regarding which information carries the greatest weight in bvFTD diagnostic evaluation. International FTLD consortia are preparing for clinical trials, though predictive tools, including current biomarkers, are inadequate to avoid erroneous inclusion of individuals who are unlikely to have either a stable bvFTD diagnosis or an FTLD pathological diagnosis. More accurate predictive tools are needed to facilitate trial enrollment and give personalized estimates of expected progression.
Statistician

4. RF1AG077557 | Co-Investigator | 6 % effort | Staffaroni (PI)
NIH/NIA | 05/01/2022 | 04/30/2025
Validating remote digital assessments for familial frontotemporal dementia | $ 2,371,437 total
The overarching goal of this project is to validate innovative, remote smartphone assessments for early disease detection and measurement of clinical disease progression in FTD.
Statistician

5. 1R01NS130066 | Co-Investigatar | 5 % effort | Morrison (PI)

	NIH/NINDS		09/01/2022	08/31/2027
	Multimodal MRI to predict DBS motor and cognitive outcomes in Parkinson's disease			$ 3,325,781 total
	The objective of this proposal is to evaluate the usefulness of preoperative fMRI, DTI, and QSM imaging data for multivariate prediction of motor and cognitive outcomes in Parkinson's disease in 100 patients receiving deep brain stimulation.			
	Statistician			
6.	PTCG-21-818270	Co-Investigator	3 % effort	Ljubenkov (PI)
	Alzheimer's Association, Inc.		10/01/2021	09/30/2024
	Veri-T: A phase 1b Placebo-Controlled Trial of Verdiperstat in FTLD-TDP			$ 2,657,600 total
	The goal of this project is to support a phase 1 multisite clinical trial of Verdiperstat (BHV-3241) in patients with semantic variant primary progressive aphasia (svPPA)			
	Statistician			
7.	P01 AG019724-21A1	Co-Investigator	5 % effort	Gorno Tempini (PI)
	NIH/NIA		06/01/2023	05/31/2028
	Frontotemporal Dementia: Genes, Images, and Emotions			
	The FTD PPG primary goal is to advance clinical practice in dementia by improving diagnosis and to further the understanding of the anatomy and biology of FTLD- spectrum disorders. The FTD PPG will benefit public health through advancing knowledge of clinical diagnostic processes, genomic, basic, translational, and clinicopathological research regarding prevalent neurodegenerative diseases and common mood disorders of aging.			
	Statistician			

RESEARCH AWARDS - PAST

1.	R01 EB00207, previously AG12119	Co-Investigator		Maudsley (PI)
	NIH/NIBIB		02/01/1996	01/31/2004
	Data Processing for MRSI		$ 133,469 direct/yr 1	$ 793,174 total
	This grant aimed to develop new techniques for magnetic resonance spectroscopic imaging data processing.			
2.	5P01AA11493	Co-Investigator		Weiner (PI)
	NIH/NIAAA		09/07/1998	08/31/2005
	Chronic Alcohol Abuse - Effects on HIV CNS Morbidity		$ 1,088,197 direct/yr 1	$ 6,541,662 total
	The major goal of this project was to determine the effects of chronic alcohol abuse on HIV, PNS, and CNS morbidity.			
3.	DAMD 17-01-1-0764	Co-Investigator		Weiner (PI)

	Department of Defense		08/01/2001	07/31/2006
	Magnetic Resonance and Spectroscopy of the Human Brain in Gulf War Illness		$ 689,203 direct/yr 1	$ 4,134,486 total

The main goal of this grant was to determine metabolite differences in Gulf War Illness subjects detectable by magnetic resonance spectroscopic imaging.

4.	R01 NS41946	Co-Investigator		Maudsley (PI)
	NIH/NINDS		08/15/2001	07/31/2006
	Proton MR Spectroscopic Imaging of Epilepsy		$ 225,000 direct/yr 1	$ 1,125,000 total

The main goal of this grant was to determine metabolite level differences in Epilepsy subjects using proton magnetic resonance spectroscopic imaging.

5.	N000014-02-1-0052	Co-Investigator		Cressie (PI)
	Office of Naval Research		10/15/2001	09/30/2004
	Spatial Statistics for Command and Control		$ 150,000 direct/yr 1	$ 482,851 total

This grant aimed to use spatial statistics methods to determine optimal strategies for command and control in the presence of potential hostile threats.

6.	K23 N8045013	Co-Investigator		Cha (PI)
	NIH		08/01/2003	04/30/2008
	Brain Tumor Imaging: Quantitative MRI and 1H MRS		$ 149,450 direct/yr 1	$ 747,250 total

The goal of this grant was to utilize traditional magnetic resonance imaging (MRI) and other physiology based imaging (such as proton MR spectroscopy, perfusion MRI) to characterize tumor malignancy and correlate MRI-derived physiologic variables with histopathology.

7.	P01AG012435	Co-Investigator		Chui (PI)
	NIH		09/30/2003	05/31/2008
	Aging Brain: Vasculature, Ischemia, and Behavior: 1H MRSI and Perfusion MRI of SIVD (Project 2)		$ 184,241 direct/yr 1	$ 963,558 total

The primary goal of this project was to address four major areas of inquiry in subcortical ischemic vascular dementia (SIVD): the role of ongoing ischemia; the role of infarction in neuron loss; the role of disconnection of subcortical and cortical structures in SIVD; and the relative differences in subcortical and cortical changes between SIVD and Alzheimer's Disease.

8.	U54 HL070587	Co-Investigator		Helms (PI)
	NIH/NHLBI		07/01/2004	03/31/2007

	Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adults with Sickle Cell Disease		$ 237,681 direct/yr 1	$ 808,428 total

Our primary role in this cooperative agreement was to act as the coordinating center for MRI. We helped select MRI scanners, and perform quality assessment at the onset of and during the study.

9.	U01 AG024904-01	Co-Investigator		Weiner (PI)
	NIH/NIA		09/30/2004	08/31/2009
	Alzheimer's Disease Neuroimaging Initiative		$ 13,515,150 direct/yr 1	$ 57,211,517 total

The primary goal of this project is to develop improved methods, which will lead to uniform standards for acquiring longitudinal, multi-site MRI and PET data on patients with Alzheimer's disease (AD), mild cognitive impairment (MCI), and elderly controls.

10.	PR043109	Co-Investigator		Weiner (PI)
	Department of Defense		10/01/2004	09/30/2008
	Magnetic Resonance Study of Amyotrophic Lateral Sclerosis and Gulf War Illness at 4 Tesla		$ 500,000 direct/yr 1	$ 2,500,000 total

The primary goal of this study was to assess the effects of Amyotrophic Lateral Sclerosis and Gulf War Illness detectable by 4 Tesla MRI of the human brain.

11.	B3776	Co-Investigator		Weiner (PI)
	Veteran's Affairs		01/01/2005	12/31/2009
	Effects of Gulf War Illness on Brain Structure, Function, and Metabolism: MRI/MRS at 4 Tesla		$ 376,950 direct/yr 1	$ 2,500,000 total

The primary goal of this project is to develop improved methods, which will lead to uniform standards for acquiring longitudinal, multi-site MRI and PET data on patients with Alzheimer's disease (AD), mild cognitive impairment (MCI), and elderly controls.

12.	R01 EB0047079	Co-Investigator		Lu (PI)
	NIH		04/01/2006	03/31/2009
	Statistical Methods for Evaluation of Diagnostic Tests		$ 180,000 direct/yr 1	$ 562,500 total

The major goal of this grant is to develop statistical methods for the evaluation of non-inferiority tests and for accurate estimation of relative risk using cross-sectional and short-term follow-up data.

13.	RG3517A	Co-Investigator		Pelletier (PI)
	National Multiple Sclerosis Society		07/01/2006	06/30/2010

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In Vivo Assessment of Glutamate in MS Using H-MRS at 3T	$ 292,129 direct/yr 1	$ 577,094 total

The major goal of this grant is to conduct a 3-year longitudinal study to evaluate the use of high field (3T) proton MR spectroscopy combined with new acquisition sequences to monitor the treatment effect in MS patients of agents that target glutamate homeostasis.

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14. SIIM	PI		Kornak (PI)
	Society for Imaging Informatics in Medicine	07/01/2007	06/30/2008
	Improved Reconstruction of Low-Resolution Magnetic Resonance Modalities	$ 31,158 direct/yr 1	$ 31,158 total

The major goal of this project was to develop statistical techniques for the improved reconstruction of perfusion weighted imaging and magnetic resonance spectroscopic imaging via the use of high-resolution anatomical prior information and k-space data modeling.

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15. HHSN267200700005C	Co-Investigator		Johansen (PI)
	NIH/NIDDK	07/01/2007	06/30/2014
	USRDS Nutritional Special Studies Center	$ 532,796 direct/yr 1	$ 2,663,980 total

The goals of this project are to investigate the effects of nutritional parameters on outcomes in ESRD using existing USRDS data and investigator-initiated data collection projects.

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16. BL01301	Co-Investigator		Lang (PI)
	National Space Biomedical Research Institute	09/01/2007	08/31/2011
	An Integrated Musculoskeletal Countermeasure Battery for Long-Duration Lunar Missions	$ 73,501 direct/yr 1	$ 681,982 total

This contract is to develop a single compact exercise device applicable to the Orion Crew Module, Lunar Lander or Lunar Base that integrates lower and upper body resistive training, cardiovascular training and sensorimotor training. Validate the efficacy of this device for reduction of bone loss, muscle loss, loss of cardiovascular function and loss of neuromuscular performance in the ongoing bedrest study at the NASA Flight Analog Center, University of Texas, Galveston.

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17. DOD	Co-Investigator		Young (PI)
	Department of Defense	08/01/2008	07/31/2010
	Information Theoretic Analysis for Sensitive Detection of Structural and Metabolic Patterns in Multimodal MR Image Studies of Head Trauma	$ 96,875 direct/yr 1	$ 193,750 total

The overall aim of this proposal is to develop sensitive diagnostic markers for mild and moderate traumatic brain injury using information theory based complexity/texture measures from multimodal MR images.

18. P41 RR023953	Project PI		Weiner (PI)
NIH/NCRR		09/15/2008	06/30/2014
NIH Resource for MRI of Neurodegenerative Disorders.		$ 1,294,990 direct/yr 1	$ 4,546,761 total

The Resource grant aims to improve acquisition, reconstruction, and processing of structural, perfusion, diffusion, and spectroscopic MRI. The project for which I am PI is titled: "Bayesian Image Reconstruction from Reduced k-Space Data". The project aims to develop and evaluate methodology to improve reconstruction of low signal-to-noise ratio perfusion MRI through incorporating high-resolution anatomical information from structural MRI.

19. UCSF Radiology Seed	PI		Kornak (PI)
UCSF, Department of Radiology and Biomedical Imaging Seed Grant		02/01/2009	07/28/2011
Quantifying Spatial Variation in the Hemodynamic Response Function Specific to Traumatic Brain Injury		$ 9,600 direct/yr 1	$ 9,600 total

This grant aims to use functional MRI and new statistical modeling approaches to determine spatial parameters of hemodynamic response shape that are indicative of traumatic brain injury.

20. REAC	PI		Kornak (PI)
UCSF REAC Pilot Research Award for Junior Investigators		06/01/2009	05/31/2011
Quantifying Spatial Variation in the Hemodynamic Response Function Specific to Alzheimer's Disease		$ 29,963 direct/yr 1	$ 29,963 total

This proposal aims to determine brain hemodynamic parameters specific to Alzheimer's disease via improved statistical modeling and spatial mapping of functional MRI responses.

21. 1. Administrative Supplement to P41 RR023953	Project PI		Weiner (PI)
NIH/NCRR		08/24/2009	08/31/2011
Administrative Supplement to NIH Resource for MRI of Neurodegenerative Disorders		$ 500,000 direct/yr 1	$ 1,000,000 total

This Administrative Supplement is part of an NIH Resource for MRI of Neurodegenerative Disorders focused on improving acquisition, reconstruction, and processing of structural, perfusion, diffusion, and spectroscopic MRI. My project as PI concerned the development of 3D k-space Bayesian Reconstruction of 3D GRASE perfusion MRI.

22. 1RC1AR058405-01	Co-Investigator		Link (PI)
NIH		09/30/2009	08/31/2011
Cortical Bone Porosity Identifies Diabetes Subjects with Fragility Fractures		$ 340,496 direct/yr 1	$ 682,264 total

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The major goal of this grant is to study cortical and trabecular bone architecture in diabetes subjects with and without osteoporotic fractures and to compare these findings to those in normal subjects and osteoporotic fracture subjects.

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23. Subcontract to: R01NS062885-01 | PI of Subcontract | Pelletier (PI)

NIH/NINDS | 10/01/2009 | 09/30/2014

Molecular and Genetic Predictors of Disability Progression in MS | $ 499,738 direct/yr 1 | $ 2,154,171 total

This project aims to determine longitudinal study to evaluate the ability of baseline glutamate to predict longitudinal NAA change and brain atrophy representative of multiple sclerosis using high field (3T) proton MR spectroscopy.

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24. R01 CA148708 | Co-Investigator | Noworolski (PI)

NIH/NCI | 07/01/2010 | 06/30/2015

DCE MRI to Improve Prostate Cancer Identification and Characterization. | $ 254,940 direct/yr 1 | $ 1,428,152 total

The goals of this grant are to improve the identification and characterization of aggressiveness of prostate cancer by utilizing novel pharmacokinetic and statistical models.

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25. CTSI-SOS | PI | Kornak (PI)

UCSF, CTSI-SOS Program | 02/01/2012 | 06/30/2013

K-Bayes for functional MRI | $ 29,962 direct/yr 1 | $ 29,962 total

The goal of this proposal is to develop a superior reconstruction procedure for functional MRI (K-Bayes) that increases the power to detect and quantify functional patterns in the human brain.

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26. CTSI-Methodology | PI | Kornak (PI)

UCSF, CTSI Consultants Methodology Award | 07/01/2012 | 06/30/2013

Targeted Learning Algorithms for Detecting Imaging Biomarkers in Large Databases | $ 20,000 direct/yr 1 | $ 20,000 total

The goal of this proposal is to develop practical learning algorithms that incorporate Bayesian imaging priors to detect disease biomarkers in large imaging databases.

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27. R01AG032306-01 | Co-Investigator | Rosen (PI)

NIH/NIA | 10/01/2009 | 09/30/2015

The Frontotemporal Lobar Degeneration Neuroimaging Initiative. | $ 1,730,132 direct/yr 1 | $ 6,940,480 total

The purpose of this project is to determine imaging modalities most useful for proving biomarkers of frontotemporal lobar degeneration in clinical trials.

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28. Komen SAC 110017	Co-Investigator		Hylton (PI)
Susan G. Komen for the Cure		12/10/2010	12/09/2015
MR Imaging Phenotypes of Breast Cancer		$ 180,354 direct/yr 1	$ 901,770 total

The goal of this project is to develop and evaluate high spatial resolution non-contrast approaches for evaluating breast tissue.

29. 1U01 CA15123	Co-Investigator		Hylton (PI)
NIH/NCI		09/26/2011	08/31/2016
Quantitative Imaging for Assessing Breast Cancer Response to Treatment		$ 493,969 direct/yr 1	$ 2,469,845 total

The goal of this project is the improved integration of MRI-based quantitative imaging (Q1) for evaluating response to treatment in clinical trials of women receiving pre-operative (neoadjuvant) treatment for breast cancer.

30. Quest	Co-Investigator	10 % effort	Hess (PI)
Quest Diagnostics Inc.		01/01/2015	10/01/2017
Dementia Pathway Neuroimaging Core Phase 1A		$ 173,382 direct/yr 1	

The goal is to work towards a system that could be deployable across different imaging platforms and would provide guidance to providers, both through standardization of acquisition and visual interpretation protocols and automated analysis to support diagnostic decision making.

Although grant is ongoing I have temporarily suspended taking funds from the grant, but will resume later as I still have funds available to me.

31. R01HL128679	Co-Investigator	8 % effort	Hu (PI)
NIH/NHLBI		07/20/2015	04/30/2019
Develop&validate SuperAlarm to Detect Patient Deterioration with Few False Alarms		$ 335,195 direct/yr 1	$ 1,675,975 total

Critical care patient monitoring remains unsatisfactory as evidenced by the alarm fatigue problem it has created. We propose to develop a data fusion framework to integrate monitor alarms, laboratory test results, and other non-monitored physiological variables to realize a more precise way of monitoring patients to provide early detection of patient crisis events with few false alarms. Our project will lead to a potentially transformative paradigm change of critical care patient monitoring towards a more integrated and precise system for recognizing crisis events and enabling early interventions and produce a database to the community to propel further development of predictive models.

Although grant is ongoing, I will only continue to help with final statistical analysis at a later date.

32. C1CMS331346-01-010	Co-Investigator	5 % effort	Miller (PI)
CMS The Centers for Medicare and Medicaid Services		09/01/2014	08/31/2017

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	The UCSF and UNMC Dementia Care Ecosystem: Using Innovative Technologies to Personalize and Deliver Coordinated Dementia Care	$ 2,721,047 direct/yr 1	$ 8,163,141 total

Most dementia care today is crisis-oriented. To break away from the cycle of stressful and costly issues that arise from a reactive approach, the Care Ecosystem will emphasize coordinated, continuous and personalized care. This proactive care model aims to improve health and satisfaction for participants and their caregivers. The study will also try to reduce avoidable emergency room visits, hospitalizations, or institutionalization, such as entering a nursing home

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33. Bluefield Project	Co-Investigator	5 % effort	Seeley (PI)
Bluefield Project to Cure FTD		06/01/2015	05/31/2017
Disease detection and monitoring: neuroimaging biomarkers for GRN mutation-related frontotemporal dementia		$ 191,197 direct/yr 1	

In this application, we propose to take on these challenges for a specific form of frontotemporal dementia (FTD) caused by mutations in GRN, which result in progranulin haploinsufficiency and a variable age at dementia onset, most commonly in mid-life. Evidence from our group and others suggests that GRN-related symptomatic FTD (henceforth GRNFTD") can be viewed as a network-based disorder in which TDP-43 inclusions, neuroinflammation, and neurodegenerative changes begin within one of three rostral brain networks involved in behavior, language, or motor function before spreading into other brain regions.

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34. U01AG04539	Co-Investigator	20 % effort	Boeve (Sub-contract PI: Rosen) (PI)
NIH - subcontract to Mayo Foundation/Mayo Clinic		09/30/2014	05/31/2019
Longitudinal Evaluation of Familial Frontotemporal Dementia Subjects (LEFFTDS)		$ 579,721 direct/yr 1	$ 2,898,605 total

The role of UCSF in the grant will be two-fold. First, UCSF will be one of three sites enrolling f-FTLD family members and performing clinical and longitudinal follow-up. UCSF will take primary responsibility for processing T1 weighted MRIs for cortical thickness, and for doing the primary PET and icfMRI processing. Lastly, UCSF will manage the secure online database that will permit direct entry of the study data from each clinical site, and assist all investigators with database queries as needed. -- Currently in no-cost extension

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35. U54NS092089	Co-Investigator	5 % effort	Boxer (PI)
NIH/NINDS		09/30/2014	07/31/2019
The Frontotemporal Lobar Degeneration Clinical Research Consortium		$ 1,250,000 direct/yr 1	$ 6,250,000 total

The overarching goal of this proposal is to build a FTLD clinical research consortium (FTLD CRC) to support the development of FTLD therapies.

36.	R01CA132870	Co-Investigator	10 % effort	Hylton (PI)
	NIH		04/28/2008	06/30/2020
	Real-time In Vivo MRI Biomarkers for Breast Cancer Pre-Operative Treatment Trials		$ 350,035 direct/yr 1	
	The goal of this project is to better enable the integration of imaging biomarkers into clinical trials by making imaging biomarkers available in real-time as part of the clinical workflow for breast MRI. Investigators at UCSF lead a large multi-center effort investigating MRI and molecular markers for assessing breast cancer response to pre-operative chemotherapy			
	Statistician			
37.		Co-Investigator	2 % effort	Scheffler (PI)
	UCSF COVID-19 Rapid Response Pilot Grant Initiative Funding Collaborative		06/01/2020	12/01/2020
	SER models for Covid-19 for Contact Tracing		$ 40,000 direct/yr 1	
	Applying SER models for Covid-19 and to study effectiveness of contact tracing			
	Co-Investigator			
38.	UL1 RR024131	Head of Biostatistics Consulting Service	10 % effort	Grandis (PI)
	NIH-NCRR		07/01/2016	06/30/2021
	Clinical and Translational Science Institute			
	The overarching goal of the Clinical and Translational Science Institute (CTSI) is to create an integrated academic home that transforms training in and conduct of clinical and translational research both at UCSF and the greater Bay Area community. Components of the CTSI include formal didactic programs, career development pathways, a variety of consultative and technical Cores, and community outreach. Dr. Kornak leads the biostatistical consulting service.			
39.	R01EB022055	Principal Investigator	5 % effort	Kornak (PI)
	NIH -- NIBIB		04/15/2017	01/31/2022
	Bayesian image analysis in Fourier space		$ 225,000 direct/yr 1	$ 900,000 total
	The objective of this project is to develop a family of new medical imaging processing methods that will provide improvements over current practices. The approach is to reformulate Bayesian Image analysis into Fourier Space (BIFS). The originally inter-correlated and high-dimensional problem in image space is broken down into a set of independent one-dimensional problems in Fourier space (tied together by the new concept of a "parameter function"). The Fourier space independence enables development of powerful and easy to specify BIFS models with fast algorithms to compute posterior image estimates. BIFS will be applied to problems in breast cancer detection and delineating patterns of brain blood perfusion associated with dementia. An open source software library will be developed for dissemination to the scientific community.			

40. R01CA227763 | Co-Investigator | 10 % effort | Hylton (PI)
NIH | 02/01/2019 | 01/31/2024

Dedicated breast PET and MRI for characterization of breast cancer and its response to therapy.

The objective of this academic-industrial partnership (AIP) project is to demonstrate the utility of dedicated breast positron emission tomography (dbPET) for characterizing primary breast cancers and their response to neoadjuvant chemotherapy (NAC).

Statistician

41. P01 AG019724 | Co-Investigator | 5 % effort | Miller (PI)
NIH/NIA | 06/01/2017 | 05/31/2022

Frontotemporal DementiaTD: Genes, Images and Emotions | $ 141,782 direct/yr 1

The overall goal of this project is to investigate the early changes in FTLD using imaging, and cognitive and behavioral assessment. Dr. Rosen directs the imaging core for the grant.

Statistician

42. R01 AG029577 | Co-Investigator | 5 % effort | Rankin (PI)
NIH/NIA | 07/01/2019 | 06/30/2024

Attention and Semantic Evaluation as Predictors of Empathy in Healthy Aging and Frontotemporal Dementia | $ 524,819 direct/yr 1

The goals of this project are to determine the value of socioemotional testing for predicting patients' clinical trajectories, and to elucidate how two selectively vulnerable neural networks contribute to normal social behavior and to the socioemotional symptoms of bvFTD. By modeling patients' socioemotional test performance over time, we will maximize our ability to predict and measure symptom progression in upcoming clinical treatment trials for bvFTD. Also, by developing our understanding of the neural network underpinnings of socioemotional behavior and empathy, we will be able to more precisely measure and monitor how these circuits malfunction to cause behavior symptoms in bvFTD and other neurologic and psychiatric disorders.

Statistician

43. R01CA227763 | Co-Investigator | 20 % effort | Hylton (PI)
NIH/NCI | 02/15/2019 | 01/31/2024

Dedicated breast PET and MRI for characterization of breast cancer and its response to therapy | $ 2,928,013 total

The objective of this academic-industrial partnership (AIP) project is to demonstrate the utility of dedicated breast positron emission tomography (dbPET) for characterizing primary breast cancers and their response to neoadjuvant chemotherapy (NAC).

Statistician

Appendix A

Prepared: May 27, 2024

PEER REVIEWED PUBLICATIONS

1. 1999 — **Kornak J,** Haggard MP, and O'Hagan A. Parameterisation of the BOLD haemodynamic response in fMRI incorporated within a Bayesian multiplicative Markov random field model. Proceedings in spatial temporal modelling and its applications. Mardia KV and Aykroyd RG editors, Leeds University Press, 27-30, 1999.

2. 2000 — **Kornak J,** Haggard MP, and Hall DA. fMRI functional mapping with alternative parameters of haemodynamic response in auditory cortex. British Journal of Audiology. 34(2):96-97, 2000.

3. 2001 — **Kornak J,** Young K, and Maudsley AA. Improved reconstruction of spectroscopic images using segmented MRIs. Proceedings in Functional and Spatial Data Analysis. Mardia KV, Aykroyd RG editors, Leeds University Press, 149-152, 2001.

4. 2002 — Hall DA, Gonçalves MS, Smith S, Jezzard P, Haggard MP, **Kornak J.** A method for determining venous contribution to BOLD contrast sensory activation. Magn Reson Imaging. 2002 Dec; 20(10):695-706. PMID: 12591565

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8. 2005 — Young K, Chen Y, **Kornak J,** Matson GB, Schuff N. Summarizing complexity in high dimensions. Phys Rev Lett. 2005 Mar 11; 94(9):098701. PMID: 15784007

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13. 2006 Leow AD, Klunder AD, Jack CR, Toga AW, Dale AM, Bernstein MA, Britson PJ, Gunter JL, Ward CP, Whitwell JL, Borowski BJ, Fleisher AS, Fox NC, Harvey D, **Kornak J,** Schuff N, Studholme C, Alexander GE, Weiner MW, Thompson PM. Longitudinal stability of MRI for mapping brain change using tensor-based morphometry. Neuroimage. 2006 Jun; 31(2):627-40. PMID: 16480900. PMCID: PMC1941663

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39. 2011 **Kornak J,** Hall DA, Haggard MP. Spatially extended FMRI signal response to stimulus in non-functionally relevant regions of the human brain: preliminary results. Open Neuroimag J. 2011; 5:24-32. PMID: 21760873. PMCID: PMC3109590

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Prepared: May 27, 2024

40. 2011 Weiner MW, Meyerhoff DJ, Neylan TC, Hlavin J, Ramage ER, McCoy D, Studholme C, Cardenas V, Marmar C, Truran D, Chu PW, **Kornak J,** Furlong CE, McCarthy C. The relationship between Gulf War illness, brain N-acetylaspartate, and post-traumatic stress disorder. Mil Med. 2011 Aug; 176(8):896-902. PMID: 21882779. PMCID: PMC3279571

41. 2011 Streeper T, Cavanagh P, Hanson A, Carpenter RD, Saeed I, **Kornak J,** Frassetto L, Grodsinsky C, Funk J, Lee SMC, Spiering BA, Bloomberg J, Mulavara A, Sibonga J, Lang T. Development of An Integrated Countermeasure Device for use in Long-Duration Space Flight. Acta Astronautica. 68(11-12): 2029-2037, 2011.

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46. 2012 Bakken TE, Roddey JC, Djurovic S, Akshoomoff N, Amaral DG, Bloss CS, Casey BJ, Chang L, Ernst TM, Gruen JR, Jernigan TL, Kaufmann WE, Kenet T, Kennedy DN, Kuperman JM, Murray SS, Sowell ER, Rimol LM, Mattingsdal M, Melle I, Agartz I, Andreassen OA, Schork NJ, Dale AM, Weiner M, Aisen P, Petersen R, Jack CR, Jagust W, Trojanowki JQ, Toga AW, Beckett L, Green RC, Saykin AJ, Morris J, Liu E, Montine T, Gamst A, Thomas RG, Donohue M, Walter S, Gessert D, Sather T, Harvey D, **Kornak J,** Dale A, Bernstein M, Felmlee J, Fox N, Thompson P, Schuff N, Alexander G, DeCarli C, Bandy D, Koeppe RA, Foster N, Reiman EM, Chen K, Mathis C, Cairns NJ, Taylor-Reinwald L, Trojanowki JQ, Shaw L, Lee VM, Korecka M, Crawford K, Neu S, Foroud TM, Potkin S, Shen L, Kachaturian Z, Frank R, Snyder PJ, Molchan S, Kaye J, Quinn J, Lind B, Dolen S, Schneider LS, Pawluczyk S, Spann BM, Brewer J, Vanderswag H, Heidebrink JL, Lord JL, Johnson K, Doody RS, Villanueva-Meyer J, Chowdhury M, Stern Y, Honig LS, Bell KL, Morris JC, Ances B, Carroll M, Leon S, Mintun MA, Schneider S, Marson D, Griffith R, Clark D, Grossman H, Mitsis E, Romirowsky A, deToledo-Morrell L, Shah RC, Duara R, Varon D, Roberts P, Albert M, Onyike C, Kielb S, Rusinek H, de Leon MJ, Glodzik L, De Santi S, Doraiswamy PM, Petrella JR, Coleman RE, Arnold SE, Karlawish JH, Wolk D, Smith CD, Jicha G, Hardy P, Lopez OL, Oakley M, Simpson DM, Porsteinsson AP, Goldstein BS, Martin K, Makino KM, Ismail MS, Brand C, Mulnard RA, Thai G, Mc-Adams-Ortiz C, Womack K, Mathews D, Quiceno M, Diaz-Arrastia R, King R, Weiner M, Martin-Cook K, DeVous M, Levey AI, Lah JJ, Cellar JS, Burns JM, Anderson HS, Swerdlow RH, Apostolova L, Lu PH, Bartzokis G, Silverman DH, Graff-Radford NR, Parfitt F, Johnson H, Farlow MR, Hake AM, Matthews BR, Herring S, van Dyck CH, Carson RE, MacAvoy MG, Chertkow H, Bergman H, Hosein C, Black S, Stefanovic B, Caldwell C, Hsiung R, Feldman H, Mudge B, Assaly M, Kertesz A, Rogers J, Trost D, Bernick C, Munic D, Kerwin D, Mesulam MM, Lipowski K, Wu CK, Johnson N, Sadowsky C, Martinez W, Villena T, Turner RS, Johnson K, Reynolds B, Sperling RA, Johnson KA, Marshall G, Frey M, Yesavage J, Taylor JL, Lane B, Rosen A, Tinklenberg J, Sabbagh M, Belden C, Jacobson S, Kowall N, Killiany R, Budson AE, Norbash A, Johnson PL, Obisesan TO, Wolday S, Bwayo SK, Lerner A, Hudson L, Ogrocki P, Fletcher E, Carmichael O, Olichney J, Kittur S, Borrie M, Lee TY, Bartha R, Johnson S, Asthana S, Carlsson CM, Potkin SG, Preda A, Nguyen D, Tariot P, Fleisher A, Reeder S, Bates V, Capote H, Rainka M, Scharre DW, Kataki M, Zimmerman EA, Celmins D, Brown AD, Pearlson GD, Blank K, Anderson K, Santulli RB, Schwartz ES, Sink KM, Williamson JD, Garg P, Watkins F, Ott BR, Querfurth H, Tremont G, Salloway S, Malloy P, Correia S, Rosen HJ, Miller BL, Mintzer J, Longmire CF, Spicer K, Finger E, Rachinsky I, Drost D, Jernigan T, McCabe C, Grant E, Ernst T, Kuperman J, Chung Y, Murray S, Bloss C, Darst B, Pritchett L, Saito A, Amaral D, DiNino M,

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Prepared: May 27, 2024

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148. 2023	Arasu VA, Habel LA, Achacoso NS, Buist DSM, Cord JB, Esserman LJ, Hylton NM, Glymour MM, **Kornak J,** Kushi LH, Lewis DA, Liu VX, Lydon CM, Miglioretti DL, Navarro DA, Pu A, Shen L, Sieh W, Yoon HC, Lee C. Comparison of Mammography AI Algorithms with a Clinical Risk Model for 5-year Breast Cancer Risk Prediction: An Observational Study. Radiology. 2023 06; 307(5):e222733. PMID: 37278627. PMCID: PMC10315521
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150. 2024	Cozen AE, Carton T, Hamad R, **Kornak J,** Faulkner Modrow M, Peyser ND, Park S, Orozco JH, Brandner M, O'Brien EC, Djibo DA, McMahill-Walraven CN, Isasi CR, Beatty AL, Olgin JE, Marcus GM, Pletcher MJ. Factors associated with anxiety during the first two years of the COVID-19 pandemic in the United States: An analysis of the COVID-19 Citizen Science study. PLoS One. 2024; 19(2):e0297922. PMID: 38319951. PMCID: PMC10846720
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152. 2024 Saloner R, Staffaroni A, Dammer E, Johnson ECB, Paolillo E, Wise A, Heuer H, Forsberg L, Lago AL, Webb J, Vogel J, Santillo A, Hansson O, Kramer J, Miller B, Li J, Loureiro J, Sivasankaran R, Worringer K, Seyfried N, Yokoyama J, Seeley W, Spina S, Grinberg L, VandeVrede L, Ljubenkov P, Bayram E, Bozoki A, Brushaber D, Considine C, Day G, Dickerson B, Domoto-Reilly K, Faber K, Galasko D, Geschwind D, Ghoshal N, Graff-Radford N, Hales C, Honig L, Hsiung GY, Huey E, **Kornak J,** Kremers W, Lapid M, Lee S, Litvan I, McMillan C, Mendez M, Miyagawa T, Pantelyat A, Pascual B, Paulson H, Petrucelli L, Pressman P, Ramos E, Rascovsky K, Roberson E, Savica R, Snyder A, Sullivan AC, Tartaglia C, Vandebergh M, Boeve B, Rosen H, Rojas J, Boxer A, Casaletto K. Large-scale network analysis of the cerebrospinal fluid proteome identifies molecular signatures of frontotemporal lobar degeneration. Res Sq. 2024 Mar 28. PMID: 38585969. PMCID: PMC10996789

153. 2024 Staffaroni AM, Clark AL, Taylor JC, Heuer HW, Sanderson-Cimino M, Wise AB, Dhanam S, Cobigo Y, Wolf A, Manoochehri M, Forsberg L, Mester C, Rankin KP, Appleby BS, Bayram E, Bozoki A, Clark D, Darby RR, Domoto-Reilly K, Fields JA, Galasko D, Geschwind D, Ghoshal N, Graff-Radford N, Grossman M, Hsiung GY, Huey ED, Jones DT, Lapid MI, Litvan I, Masdeu JC, Massimo L, Mendez MF, Miyagawa T, Pascual B, Pressman P, Ramanan VK, Ramos EM, Rascovsky K, Roberson ED, Tartaglia MC, Wong B, Miller BL, **Kornak J,** Kremers W, Hassenstab J, Kramer JH, Boeve BF, Rosen HJ, Boxer AL, ALLFTD Consortium. Reliability and Validity of Smartphone Cognitive Testing for Frontotemporal Lobar Degeneration. JAMA Netw Open. 2024 Apr 01; 7(4):e244266. PMID: 38558141. PMCID: PMC10985553

BOOKS AND CHAPTERS

1. 2006 Du, A.T., Schuff, N., Chao,L.L. , Kornak, J., Ezekiel, F., Jagust, W.J., Kramer, J.H., Reed, B.R., Miller, B.L., Norman, D., Chui, H.C., Weiner, M.W. White matter lesions are associated with cortical atrophy more than entorhinal and hippocampal atrophy. Eds: Nishimura and A. Gregory Sorensen. International Congress Series, Publisher: Elsevier. 1290, 89-100, 2006

2. 2017 Zhao, Q., Lu, Y., **Kornak, J.** Medical Signal and Image Analysis. In Handbook of Medical Statistics. Ed: Fang Ji-Qian. 737-763, 2017

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OTHER PUBLICATIONS

1. 2005 **Kornak, J.,** and Young, K. - On the comparison of analytic optimization algorithms for the reconstruction of low-resolution k-space data in high-resolution transformed space. Proceedings of CMM 2005 - Computational Methods in Mechanics, Czestochowa, Poland, 2005.

2. 2014 **Kornak, J.** - Bayesian image analysis in Fourier space (BIFS). In JSM Proceedings, Statistics in Imaging Section. Alexandria, VA: American Statistical Association. 1487-1492. 2014.

3. 2020 **Kornak J,** Boylan R, Young K, Wolf A, Cobigo Y, Rosen H. Bayesian Image Analysis in Fourier Space Using Data-Driven Priors (DD-BIFS). In International Conference on Information Processing and Management of Uncertainty in Knowledge-Based Systems 2020 Jun 15 (pp. 380-390). Springer, Cham.

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SIGNIFICANT PUBLICATIONS

1. 2019 **Kornak J,** Fields J, Kremers W, Farmer S, Heuer HW, Forsberg L, Brushaber D, Rindels A, Dodge H, Weintraub S, Besser L, Appleby B, Bordelon Y, Bove J, Brannelly P, Caso C, Coppola G, Dever R, Dheel C, Dickerson B, Dickinson S, Dominguez S, Domoto-Reilly K, Faber K, Ferrall J, Fishman A, Fong J, Foroud T, Gavrilova R, Gearhart D, Ghazanfari B, Ghoshal N, Goldman J, Graff-Radford J, Graff-Radford N, Grant IM, Grossman M, Haley D, Hsiao J, Hsiung R, Huey ED, Irwin D, Jones D, Jones L, Kantarci K, Karydas A, Kaufer D, Kerwin D, Knopman D, Kraft R, Kramer J, Kukull W, Lapid M, Litvan I, Ljubenkov P, Lucente D, Lungu C, Mackenzie I, Maldonado M, Manoochehri M, McGinnis S, McKinley E, Mendez M, Miller B, Multani N, Onyike C, Padmanabhan J, Pantelyat A, Pearlman R, Petrucelli L, Potter M, Rademakers R, Ramos EM, Rankin K, Rascovsky K, Roberson ED, Rogalski-Miller E, Sengdy P, Shaw L, Staffaroni AM, Sutherland M, Syrjanen J, Tartaglia C, Tatton N, Taylor J, Toga A, Trojanowski J, Wang P, Wong B, Wszolek Z, Boeve B, Boxer A, Rosen H. Nonlinear Z-score modeling for improved detection of cognitive abnormality. Alzheimers Dement (Amst). 2019 Dec; 11:797-808. PMID: 31872042. PMCID: PMC6911910

   The work in this paper was developed for the ALLFTD Consortium whose aim is to examine longitudinal Frontotemporal Lobar Degeneration. The project arose because conventional linear approaches to develop normative neuropsychological scores that account for age and educational level were found to be inadequate leading to counter-intuitive results. These results occurred because of the linear and constant variance assumptions inherent to the linear models that are in standard use for normative scores. For this paper we extended the conventional approach to use shape-constrained additive models such that both non-linear monotonic effects can be modeled, and non-constant variance incorporated. This new approach has led to normative score calculators that clinicians feel are more consistent with expectations and it has been adopted within the ALLFTD study and is beginning to be used more widely.

2. 2023 Casaletto, K. B., **Kornak, J.,** Paolillo, E. W., Rojas, J. C., VandeBunte, A., Staffaroni, A. S., ... & ALLFTD Consortium. (2023). Association of physical activity with neurofilament light chain trajectories in autosomal dominant frontotemporal lobar degeneration variant carriers. JAMA neurology, 80(1), 82-90.

This paper provides an example of my collaborative work. My extensive knowledge on statistical methods for working with longitudinal methods in dementia using imaging and other biomarker data. My objective when working on such projects is to work in a trans-disciplinary fashion such that there is a synergy between the clinical expertise and optimizing experimental design and statistical strategy. I worked as an advisor to a large degree on this project. Dr. Casaletto, the lead author, has asked me to be a statistical mentor on her NIH K-award application. Working this way means that I often act as a "teacher" while also helping directly with the experimental planning and statistical analysis.

3. 2011 **Kornak J,** Lu Y. Bayesian decision analysis for choosing between diagnostic procedures (with an application in osteoporotic hip fracture assessment). Statistics and Its Interface. 2011; 4:27-36. PMID: 23243483. PMCID: PMC3520495.

This paper describes a quantitative technique to aid the decision of whether to adopt a new diagnostic method. The decision process for diagnostic procedures is complicated by the fact that diagnostic decisions are typically based on thresholding one or more continuous variables. Therefore, my formal decision process accounts for uncertainty in the optimal threshold value for each diagnostic procedure. My approach uses a Bayesian decision approach based on maximizing expected utility (incorporating patient-benefit, accuracy and costs) with respect to diagnostic procedure and threshold level simultaneously. I proposed the original idea, developed the method, wrote the code, ran the applications, and wrote the paper.

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4. 2010 **Kornak J,** Young K, Soher BJ, Maudsley AA. Bayesian k -space-time reconstruction of MR spectroscopic imaging for enhanced resolution. IEEE Trans Med Imaging. 2010 Jul; 29(7):1333-50. PMID: 20304734. PMCID: PMC2911978

This paper provides a comprehensive description of the development and implementation of K-Bayes for magnetic resonance spectroscopic imaging (MRSI.). There is a comprehensive mathematical development of the K-Bayes reconstruction methodology for MRSI, along with multiple applications and simulation studies. The K-Bayes MRSI model extends on the model for perfusion MRI in manuscripts 29 and 30 via the additional consideration of a time dimension, thereby adding an extra level of complexity and computational difficulty. MRSI data sets consists of a time series at each k-space point that itself consists of overlapping metabolite signals each occurring at the their own resonance frequencies and with their own rates of exponential decay. The K-Bayes MRSI model incorporates a full k-space-time likelihood model for the signal over a set of metabolites and combines it with an anatomical prior model based on structural MRI. The ensuing posterior distribution is maximized to provide a set of reconstructed metabolite maps. I had the initial idea of developing K-Bayes for reconstructing MRSI, developed the K-Bayes model for MRSI and associated computational algorithm for the reconstruction procedure, implemented the procedure, ran the applications and wrote the paper.

5. 2009 **Kornak J,** Dunham B, Hall DA, Haggard MP. Nonlinear voxel-based modeling of the haemodynamic response function in fMRI. Journal of Applied Statistics. 36(3): 237-253, 2009.

This paper presents new non-linear models of the brain hemodynamic response (HDR) to stimuli, actions or thoughts capable of capturing response shape characteristics missed by standard models. The application of these new models to fitting the HDR in this paper demonstrates coherent spatial variation in response shape within regions of brain activation. Understanding and properly modeling these spatial variations in HDR shape could have important implications for understanding hemodynamic brain changes due to neurodegenerative diseases, psychiatric illnesses or/and brain injury. For this paper, I had the initial idea to reformulate models for the HDR, performed all model development and application, and wrote the paper.

OTHER CREATIVE ACTIVITIES

1. 2005-06 Course notes and Powerpoint presentations for the Statistics for Radiology course and the lecture series for Radiology Residents
   2006 Powerpoint presentations for tutorials presented at Center for Imaging of Neurodegenerative Diseases (VA Medical Center)
   2006-07 Powerpoint presentation for Medical Imaging Informatics lecture
   2009 Powerpoint presentations for Statistics for Radiology and Biomedical Imaging course
   2011-15 Revised lecture Powerpoint presentations for TICR Biostat 209 course
   2016-17 Developed course notes and lectures for TICR Biostat 202 course
   2017-18 Developed course notes and lectures for TICR Biostat 216 course

2. See statistical review lectures under "Invited Presentations."

Appendix B

Materials Considered List

Academic Articles and Books

- Azur, M. J., Stuart, E. A., Frangakis, C., & Leaf, P. J. (2011). Multiple imputation by chained equations: what is it and how does it work?. *International Journal of Methods in Psychiatric Research*, 20(1), 40-49.
- Chang, C. J., O'Brien, K. M., Keil, A. P., Goldberg, M., Taylor, K. W., Sandler, D. P., & White, A. J. (2024). Use of personal care product mixtures and incident hormone-sensitive cancers in the Sister Study: a US-wide prospective cohort. *Environment International*, 183, 108298.
- Gonzalez, N. L., O'Brien, K. M., D'Aloisio, A. A., Sandler, D. P., & Weinberg, C. R. (2016). Douching, talc use, and risk of ovarian cancer. *Epidemiology*, *27*(6), 797-802.
- Goodman, J. E., Espira, L. M., Zu, K., & Boon, D. (2024). Quantitative recall bias analysis of the talc and ovarian cancer association. *Global Epidemiology*, *7*.
- Goodman, J. E., Kerper, L. E., Prueitt, R. L., & Marsh, C. M. (2020). A critical review of talc and ovarian cancer. *Journal of Toxicology and Environmental Health, Part B*, *23*(5), 183-213.
- O'Brien, K. M., Ogunsina, K., Wentzensen, N., & Sandler, D. P. (2023). Douching and genital talc use: patterns of use and reliability of self-reported exposure. *Epidemiology*, *34*(3), 376-384.
- O'Brien, K. M., Tworoger, S. S., Harris, H. R., Anderson, G. L., Weinberg, C. R., Trabert, B., ... & Wentzensen, N. (2020). Association of powder use in the genital area with risk of ovarian cancer. *JAMA*, 323(1), 49-59.
- O'Brien, K. M., Wentzensen, N., Ogunsina, K., Weinberg, C. R., D'Aloisio, A. A., Edwards, J. K., & Sandler, D. P. (2024). Intimate care products and incidence of hormone-related cancers: A quantitative bias analysis. *Journal of Clinical Oncology*, JCO-23.
- O'Brien, K. M., Sandler, D. P., & Wentzensen, N. (2020). Genital Powder Use and Ovarian Cancer—Reply. *JAMA*, *323*(20), 2096-2097.
- Rubin, D. B., 1987. Multiple Imputation for Nonresponse in Surveys. New York: John Wiley & Sons.
- Tompsett D.M., Leacy F., Moreno-Betancur M., Heron J., White I.R. On the Use of the Not-at-Random Fully Conditional Specification (NARFCS) Procedure in Practice. *Statistics in Medicine*. 2018 Jul 10;37(15):2338-53.
- Trabert, B., Poole, E. M., White, E., Visvanathan, K., Adami, H. O., Anderson, G. L., ... & Ovarian Cancer Cohort Consortium (OC3). (2019). Analgesic use and ovarian

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cancer risk: an analysis in the Ovarian Cancer Cohort Consortium. JNCI: *Journal of the National Cancer Institute*, 111(2), 137-145.

- Wentzensen, N., & O'Brien, K. M. (2021). Talc, body powder, and ovarian cancer: a summary of the epidemiologic evidence. *Gynecologic Oncology*, *163*(1), 199-208.

Data, Public Sources, and Websites

- Common Biostatistical Problems and the Best Practices that Prevent Them, Problem 6. Overuse Of Multiple Comparisons Adjustments. UCSF, available at https://web.archive.org/web/20221002072642/https://wiki.library.ucsf.edu/display/BIOSTAT/Common+Biostatistical+Problems+and+the+Best+Practices+that+Prevent+Them.

- Editor-in-Chief of the International Journal of Gynecological Cancer (IJGC) Dr. Pedro Ramirez. (Host). (2020, September 14). Use of Talcum Powder and Risks of Ovarian Cancer with Katie O'Brien [Audio podcast episode]. In IJGC Podcast. BMJ Talk Medicine. https://ijgcbmj.podbean.com/e/use-of-talcum-powder-and-risk-of-ovarian-cancer-with-katie-o-brien-1684257943/.

- Google Trends, "talc cancer," available at https://trends.google.com/trends/explore?date=all&geo=US&q=talc%20cancer&hl=en, accessed on March 28, 2024.

- National Cancer Institute Dictionary of Cancer Terms, "Hazard Ratio," National Institute of Health, available at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/hazard-ratio.

- Personal Care Questionnaire, The Sister Study, available at https://sisterstudy.niehs.nih.gov/English/images/docs/PersonalCare-v3-508.pdf (Enrollment Questionnaire).

- The Sister Study, Health, Medical History and Lifestyle, available at https://sisterstudy.niehs.nih.gov/English/images/docs/SIS_DFU4_2018_vA_07182018.pdf (Follow-Up Questionnaire).

Note: In addition to any materials on this list, I considered all documents and data cited in my report.